Colleen Mone
Plaintiff in *Propria Persona*
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**UNITED STATES DISTRICT COURT**

**EASTERN DISTRICT OF NEW YORK**

**225 Cadman Plaza East, Brooklyn, NY 11201**

COLLEEN MONE

PLAINTIFF,

v. CASE NO. 1:21-cv-06915

NEW YORK STATE
UNIFIED COURT SYSTEM
DEFENDANT.

_____/

**AMENDED COMPLAINT & DEMAND FOR JURY TRIAL**

**Preliminary Statement about Amended Complaint**

The complaint is amended by order of the court. Plaintiff objects to the court allowing the defendant to make a general statement in an undated letter to the court, that was filed with the court on March 28th 2022, as Docket Document 17, about "intending" to file a motion to dismiss, which fails to comply with Rule 7(b). The defendant never filed such motion, yet the court relied upon this commentary to order the plaintiff to amend the pleading.

Two reasons given in the defendant's letter demonstrate a pure lack of understanding of disability law. The burden of proof is not upon the plaintiff, it is because the defendant has failed to meet its burden of proof that the facts have given rise to the commencement of this complaint.

The plaintiff does not have the burden to prove that the defendant regarded the plaintiff as having a disability because she was already regarded as having a disability. It does not matter whether or not the defendant regarded the plaintiff as having a disability. The plaintiff gave adequate notice that she was a qualified individual with a disability and that she was already regarded as having a disability (not that the defendant regarded her as having a disability).

Ironically, the defendant's so-called "Covid" policies demonstrate that it did regard the plaintiff as having a contagious disease (disability), even though this fact is not necessary to satisfy the pleading requirements.

Furthermore, it is well-documented in the pleading that while this satisfies the "regarded as" prong under the ADA, the defendant did in fact also make a "record of" such disability by mis-classifying the plaintiff as having an impairment that could only be cured by its so-called "Covid" policies, which were in fact not job-related.

It is a violation of 42 USC 12203(b) to require one claiming to have a disability to discuss the nature of such disability under the circumstances. The complaint is based upon the defendant's refusal to comply with Section 504 of the Rehabilitation Act of 1973, as it is applied under the standards of Title I of the Americans with Disabilities Act.

It was the defendant who failed to meet its burden of proof that it was exempt from having to comply with the ADA. To wit, the defendant ignored, refused and denied plaintiff's claim that she was a qualified individual with a disability, and that she was regarded as having a disability.

The defendant failed to conduct any individualized assessment to determine if the plaintiff was a direct threat. This would have exempted the defendant from its legal duty under disability law as cited herein. The defendant failed to establish any other exemptions that would have excused itself from having to comply with the ADA, specifically, imposing accommodations upon the plaintiff in violation of 29 CFR Part 1630.9(d).

Plaintiff, Colleen Mone ("plaintiff"), files this Complaint against defendant, NEW YORK STATE UNIFIED COURT SYSTEM ("defendant") and states as follows:

## INTRODUCTION

**1.** This is a claim by plaintiff Colleen Mone against her employer for violations of the Americans with Disabilities Act ("ADA") and the Americans with Disabilities Amendments Act ("ADA-AA"), 42 U.S.C. § 12101, *et sequitur* for discrimination and retaliation on the basis of disability; for prohibited actions taken on the basis of this disability under the "regarded as" prong and the "record of" prong; and for declaratory and injunctive relief under Title I of the Americans with Disabilities Act as implemented under 29 CFR Part 1630, *et sequitur.*

**2.** Accordingly, plaintiff brings this action pursuant to the ADA and ADA-AA to recover all available relief in law, including but not limited to: (i) a judgment from this Court that defendant's actions were unlawful; (ii) back pay; (iii) compensatory damages in whatever amount she is found to be entitled; (iv) reinstatement, or in the alternative front pay in the event reinstatement is not practical; (v) an equal amount as liquidated damages, other monetary damages; (vi) an award of costs and reasonable court fees; and (vii) punitive damages to the extent available; (viii) pre-judgment and post-judgment interest; and (ix) a jury trial on all issues so triable.

## JURISDICTION AND VENUE

**3.** This court has original and exclusive jurisdiction over plaintiff's claims pursuant to 28 U.S.C. §1331, in that the matters in controversy are brought pursuant to Title I of the Americans with Disabilities Act of 1990 and the ADA and ADA-AA of 2008; 42 U.S.C. §12101 and 42 U.S.C. §12112(a), (b) and (d)(4) as it pertains to "Discrimination"; as implemented by 29 CFR Part 1630.14(b)(3), (c) & (d) as it pertains to adverse employment actions, employers and medical examinations and interventions.

**4.** Venue is proper in this judicial district under 28 U.S.C. §1391 because defendant does business in this judicial district and the acts complained of took place in this judicial district.

**5.** Plaintiff timely filed a charge of Discrimination against the defendant with the Equal Opportunity Employment Commission (EEOC) on or about the date of September 21, 2021.

**6.** On or about December 7, 2021, the EEOC issued plaintiff a Notice of Right to Sue against defendant with regards to this matter. A copy of the Right to Sue letter is attached as Exhibit A-12.

**7.** Plaintiff has exhausted the administrative remedies available to her.

**8.** Plaintiff filed her original complaint within 90 days of the EEOC's issuance of the notice of right to sue.

## PARTIES

**9.** Plaintiff, Colleen Mone, resides in Staten Island, New York at the address of 83 Windsor Road and is a qualified individual with a disability within the meaning of the ADA and ADA-AA.

**10.** Plaintiff was an employee of the defendant, which is a "covered entity" within the meaning of the ADA and ADA-AA.

**11.** Defendant's principal place of business is located at 25 Beaver Street, New York, New York.

**12.** At all times material to this action, Plaintiff was an "employee" of defendant within the meaning of the ADA and ADA-AA.

**13.** At all times relevant, defendant was an "employer" as defined by 42 U.S.C. 12111(5).

**14.** From approximately January 23, 2006, until her termination on October 19, 2021, plaintiff was employed as a Court Officer for the defendant for sixteen years.

**15.** At all times material to this action, plaintiff was perceived as having a disability as defined by 42 U.S.C. §12102 (1) (2) and (3) and was subjected to adverse actions prohibited under this chapter because of perceived physical impairments whether or not these perceived impairments limited or were perceived to limit major life activities.

**16.** Specifically, plaintiff was perceived as disabled with a contagious disease; was mis-classified as having an impaired immune system and an impaired respiratory system by defendant; and was not allowed to work because of defendant's discriminatory perceptions, policies and procedures.

**17.** At all times material to this action, plaintiff was, and is, a "qualified individual" under the ADA and ADA-AA as a person who met the legitimate skill, experience, education, or other requirements of the employment position that plaintiff held, and who can/could perform the "essential functions" of the position plaintiff held with or without reasonable accommodation.

**18.** Additionally, defendant is not eligible for any exemption under the ADA and ADA-AA, and, indeed, did not seek or obtain an exemption.

**19.** At all times material to this action, defendant is/was an employer covered by the ADA and ADA-AA in that it employs more than 15 employees.

**20.** At all times material to this action, defendant has waived sovereign immunity. Congress waives sovereign immunity for state agencies from an action in Federal court for violations of the ADA. 42 USC 12202 as implemented in 28 CFR § 35.178.

**21.** At all times material to this action, plaintiff was an employee entitled to be free from discrimination on the basis of a perceived disability under the ADA and ADA-AA.

## PLAIN STATEMENT

**22.** Defendant's policies and procedures demonstrate that it discriminated against plaintiff based upon perceived disability. When plaintiff objected, the defendant continued to impose accommodations; including but not limited to: medical examinations, medical interventions including mask-wearing; without first conducting an individualized assessment to determine if she was a direct threat. Defendant used policies and procedures to harass, isolate, segregate, limit, classify, deny equal access and impose non-job-related medical exams and inquiries upon plaintiff. Defendant also retaliated against plaintiff by interfering with her rights, imposing punitive measures including requiring medical examinations, removing her from scheduled work-shifts, falsely declaring her unfit for service and

ultimately terminating her employment on the basis of disability, which is prohibited under the ADA and ADA-AA.

**STATEMENTS OF FACT**

**23.** The Americans with Disabilities Act Amendments Act ("ADA and ADA-AA"), 42 U.S.C. § 12101, et. seq., as amended is a remedial statute aimed at addressing and providing remedy in response to Congress's findings that discrimination against individuals with physical or mental disabilities persist in critical areas like employment, and our nation's goals with respect to individuals with disabilities is to assure equality of opportunity and participation. 42 U.S.C. § 12101(a)(1)-(8). The ADA and ADA-AA is meant to protect qualified employees, like plaintiff, from discrimination, harassment and retaliation in the workplace on account of a real or perceived mental or physical disability. 42 U.S.C. § 12112.

**24.** Plaintiff advised defendant that she was being regarded as disabled by the defendant and that the defendant was making a record of this disability by mis-classifying her as substantially limited with impaired immune and respiratory systems affecting her ability to perform major life activities in the workplace including working, communicating with others, performing manual tasks, talking, and breathing without the use of mitigation measures.

**25.** Plaintiff on many occasions duly noticed defendant of her good faith opposition to discriminatory policies and procedures.

**26.** Under the ADA and ADA-AA an employer may not require an individual with disability to accept accommodations which such qualified individual chooses not to accept. 29 CFR 1630.9 (d). This is especially pertinent when accommodations are imposed for a perceived and unproven disability.

**27.** Under the ADA and ADA-AA an employer is required to conduct an individual assessment to determine whether an employee poses a 'direct threat' before it can impose any measures upon the employee. 29 CFR §1630.2 (r)

**28.** Under the ADA and ADA-AA it is considered discrimination on the basis of disability if the employer limits, segregates, or classifies an employee in a way that adversely affects such employee because of the disability. 42 USC § 12112

**29.** Under the ADA and ADA-AA an employer who discharges, disciplines, or discriminates against an employee in the manner described in subsection (a) is considered to have violated 29 CFR §1630.4 (a)

**30.** Under the ADA and ADA-AA employers are prohibited from retaliating against individuals who oppose discriminatory activities or who make charges, testify, assist, or participate in any manner in an investigation, proceeding or hearing. 42 U.S.C. § 12203 and 29 CFR Parts 1630.12(a) and (b) and Parts 1630.13(b), (c), (d) and Part 1630.14(c) and shall be subject to the enforcement provisions relevant to such violations set forth in sections 42 U.S. Code § 12117, 42 U.S. Code § 12133 and 42 U.S. Code § 12188.

**31.** Under the ADA and ADA-AA employers are prohibited from requiring medical examinations or making disability-related inquiries of employees unless such examination or inquiry is shown to be job-related and consistent with business necessity; 42 U.S.C. §12112(d)(4); 29 CFR §1630.13 (b).

**32.** Under the ADA and ADA-AA, employers are prohibited from sharing non-job-related medical classification without any regard to confidentiality; 29 CFR §1630.14 (c).

**33.** Plaintiff may proceed under the "regarded as" prong and the "record of" prong and this court has jurisdiction under these prongs of the ADA and ADA-AA.

## GENERAL ALLEGATIONS

**34.** At all times material to this action, defendant failed to comply with its duty under the ADA and ADA-AA.

**35.** Plaintiff notified defendant that she was a qualified individual with disability because she was being regarded as disabled with a contagious disease by the defendant's policies and procedures.

**36.** Defendant's policies and procedures are specifically implemented for the purpose of mitigating the disability which it regards plaintiff as having.

**37.** Defendant misclassified plaintiff as substantially limited and refused to allow plaintiff to perform several major life activities without using mitigation measures.

**38.** When plaintiff chose not to accept the defendant's offered accommodations per 29 CFR 1630.9 (d), the defendant retaliated against plaintiff.

**39.** Defendant was required to either provide equal access or claim exemption to the ADA and ADA-AA and it did neither; thus defendant failed to perform its duty under the ADA and ADA-AA.

**40.** Defendant discriminated and retaliated against plaintiff for making a complaint that she was being regarded as disabled, thus asserting her entitlement to equal access under the ADA and ADA-AA.

**41.** Plaintiff requested the defendant to provide a copy of the individualized assessment[1] that it conducted to determine that plaintiff was a direct threat; however, defendant ignored the requirement and continued to demand that plaintiff participate in its "health control measures" or accommodations such as mask-wearing, medical examinations, inquiries and treatments under Emergency Use Authorization ("EUA").

**42.** Rather than providing equal access or proving any exemption to complying with the ADA and ADA-AA, defendant embarked on a series of adverse employment actions against plaintiff which were designed to deter plaintiff's good faith opposition to the policies and procedures.

**43.** Defendant's policies and procedures segregated the plaintiff based on physical condition.

**44.** Defendant's policies and procedures limited plaintiff's access to the workplace based on perceived disability.

1 EEOC Technical Manual 2.2 (c) "...the Supreme Court has stated and the Congress has reiterated, "society's myths and fears about disability and disease are as handicapping as are the physical limitations that flow from actual impairments." The legislative history of the ADA indicates that Congress intended this part of the definition to protect people from a range of discriminatory actions based on "myths, fears and stereotypes" about disability, which occur even when a person does not have a substantially limiting impairment."

**45.** Defendant's policies and procedures refused to allow plaintiff to perform her employment duties without using mitigation measures.

**46.** Defendant's policy and procedures limited plaintiff's right to invoke ADA and ADA-AA protections by refusing to recognize that plaintiff could claim a reason under Federal law for refusing to comply with the policy and procedures. Instead, defendant insisted that plaintiff could only claim a "medical" or "religious" exemption, which is interference with plaintiff's rights under the ADA and ADA-AA.

**47.** Defendant also engaged in adverse employment actions when plaintiff claimed the right of informed consent and the right to refuse to take part in clinical trials and noticed defendant that all the imposed mitigation measures fall under an EUA period.

**48.** Defendant's violation of the ADA and ADA-AA was not in good faith and was willful, and plaintiff sustained damages as a result of defendant's conduct including past and future earnings, lost opportunities and benefits, liquidated damages, emotional distress, and reasonable attorneys' fees and or costs.

**49.** Plaintiff re-alleges each statement from the affidavit herein.

## COUNT I

## DISCRIMINATION UNDER THE ADA and ADA-AA FOR PERCEIVED DISABILITY

**50.** Plaintiff incorporates each of the above statements of fact herein; the allegations contained in the paragraphs 1 through 48 and the plaintiff's supporting affidavit which is also re-alleged and incorporated herein by reference.

**51.** Title I of the ADA prohibits employment discrimination on the basis of disability in all aspects of employment, in 29 CFR § 1630 *et sequitur;* and particularly §1630.4; § 1630.5.

**52.** Plaintiff is a qualified individual under the ADA and ADA-AA.

**53.** On September 1, 2021, defendant began regarding plaintiff as having the disability of a contagious disease and made a record of such disability by mis-classifying plaintiff as being substantially limited with an impaired immune system and an impaired respiratory

system; and began requiring plaintiff to use mitigation measures to perform several major life activities in the workplace.

**54.** Defendant failed to conduct an individualized assessment to determine whether plaintiff met the criteria of posing a direct threat. Defendant only referred to statements made on the CDC's website which does not qualify as an individualized assessment.

**55.** Despite having knowledge of plaintiff claiming protected status under the ADA and ADA-AA, defendant continued to limit, segregate, classify plaintiff due to its perception of plaintiff as a person with a disability within the meaning of the ADA and ADA-AA.

**56.** Defendant's responses to the requests made by plaintiff to cease the discrimination and harassment were in fact non-responsive, dismissive or harassing; a true and correct copy of each written communication is included with Exhibit A.

**57.** Despite plaintiff's written notices, defendant continued without cessation to harass the plaintiff based upon disability by sending plaintiff numerous communications coercing plaintiff to accept various accommodations or suffer adverse employment actions. All written communications are attached as Exhibit A.

**58.** Defendant has failed to ensure the plaintiff equal access to the premises where plaintiff was assigned to work; and the plaintiff has been prevented from enjoying equal access to the benefits of employment enjoyed by other employees.

**59.** Defendant's "COVID-19 policies and procedures" classified plaintiff in such a way that plaintiff's employment opportunities were adversely affected and limited because defendant would not permit plaintiff to do her job without first submitting to defendant's accommodations ("mitigation measures").[2]

**60.** Defendant required non-job-related medical examinations or made disability-related inquiries[3] of plaintiff that were not consistent with business necessity. Defendant has also failed to provide any notice as to the manner in which these inquiries or medical examinations were an essential function of plaintiff's job.

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2 Prohibited by 29 CFR § 1630.5

3 Prohibited by 42 U.S.C. §12112(d)(4); 29 CFR §1630.13 (b)

**61.** An employer is entitled only to the information necessary to determine whether the employee can perform the essential functions of the job[4] with or without reasonable accommodations.

**62.** Defendant never conspicuously disclosed or gave legally adequate notice that complying with the COVID-19 mitigation measures ("accommodations") are an **essential function** of the job of a Court Officer; and these measures have never previously been an essential function of plaintiff's job, and also did not mention plaintiff's right of refusal under EUA guidelines[5].

**63.** Plaintiff claimed her right not to provide any medical information that is not related to the performance of her job duties.

**64.** Defendant also limited the accommodation measures[6], such as examinations; disclosures of medical records that were not job-related; experimental injections; medical interventions; equipment or products; to only those chosen by defendant. Additionally, defendant failed to prove that there are no other accommodations available which do not require injections, medical devices and medical examinations.

**65.** Defendant classified plaintiff as "unvaccinated"[7]; widely shared this classification of plaintiff with other employees without any regard to confidentiality[8]; and encouraged employees to harass plaintiff with repetitive emails, intimidating interactions and threats of termination.

**66.** If plaintiff had previously made at least one request for reasonable modifications, plaintiff has since withdrawn such request.

**67.** Additionally, the experimental "vaccines" that are being promoted as vaccines do not actually prevent transmission or infection of any contagious disease, specifically regarding the "COVID-19" or "SarsCOV2" purported "diseases".

4 29 CFR 1630.2(n)(2) definition "Essential Function": "(i) ….the reason the position exists is to perform that function."

5 Title 21, Chapter 9 V, Part E §360bbb–3a. Emergency use of medical products.

6 29 CFR Part 1630.2(j)(5)(i)

7 Discrimination based upon physical condition

8 Prohibited by 29 CFR § 1630.13.

**68.** The ADA and ADA-AA also protects individuals such as plaintiff for whom submitting to certain accommodation measures would create impairments. The accommodations include, but are not limited to, taking experimental injections under Emergency Use Authorization (EUA) which are being promoted as "vaccines" but which are not legally vaccines; submitting to repetitive, non-job-related medical examinations (nasal tissue testing, temperature checks); being placed under isolation, segregation and quarantine without due process; using medical devices for mitigation measures[9] (masks); disclosing plaintiff's medical records and history for non-job-related matters and participating in clinical trials and epidemiological experiments as a condition of employment.

**69.** Plaintiff requests that this court take judicial notice of Section 201(h) of the Food, Drug and Cosmetic Act and its Final Guidance titled, "Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff", published in September of 2017[10], in which the Food & Drug Administration **defines** wearing a mask for mitigation purposes as a medical device and the application of a medical device or contrivance.

**70.** Plaintiff further requests judicial notice of the fact that the Food & Drug administration has never **approved** wearing such face masks, but only "authorized" them without any supporting medical or clinical data establishing any medical necessity or efficacy for wearing such contrivances.

**71.** Plaintiff requests that the court take judicial notice of the official mortality rates of the State of New York and the United States for the years from 2017, 2018, 2019 and 2020 in which the standard deviation is zero, the very definition of no verifiable "pandemic".

**72.** Plaintiff has been damaged by defendant's violation of the ADA and ADA-AA and has suffered damages, which include past and future earnings, lost opportunities and benefits, and emotional distress.

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9 Section 201(h) Food, Drug & Cosmetic Act

10 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-products-drugs-and-devices-and-additional-product-classification-issues

**73.** The conduct of defendant and its agents and employees proximately, directly, and foreseeably, injured plaintiff, including but not limited to, emotional pain and suffering, humiliation, inconvenience, mental anguish, loss of enjoyment of life, and other non-pecuniary losses.

**74.** The conduct of defendant was so willful and wanton and in such reckless disregard of the statutory rights of plaintiff so as to entitle her to an award of punitive damages against defendant, to deter it, and others, from such conduct in the future.

**75.** As a result of defendant's actions plaintiff has experienced discrimination, harassment, segregation, isolation.

**76.** Plaintiff is entitled to any and all relief permitted under the ADA and ADA-AA, 42 U.S.C. § 12117(a), including equitable relief.

**77.** **WHEREFORE**, Plaintiff respectfully requests entry of:

a. judgment in her favor and against defendant for violation of the anti-discrimination provisions of the ADA and ADA-AA;

b. ordering defendant to comply with the requirements of Title I of the Americans with Disabilities Act, 42 U.S.C. §12101; and

c. ordering defendant to take such affirmative steps as may be necessary to prevent the recurrence of any discriminatory conduct and to eliminate, to the extent practicable, the effects of such conduct.

d. judgment in plaintiff's favor and against defendant for actual and compensatory damages, including lost earnings, front pay, and/or all actual monetary losses suffered as a result of defendant's conduct;

e. judgment in plaintiff's favor and against defendant for plaintiff's reasonable attorney fees, costs and litigation expenses;

f. judgment in plaintiff's favor and against defendant for punitive damages; and

g. an order granting such other and further relief as this Court deems just and equitable under the circumstances of this case.

**78.** Plaintiff demands a jury trial.

## COUNT II

## INTERFERENCE/RETALIATION UNDER THE ADA and ADA-AA

**79.** The ADA and ADA-AA also prohibits employers from retaliating against individuals who oppose discriminatory activities or who make charges, testify, assist, or participate in any manner in an investigation, proceeding or hearing under the ADA, Title 42 U.S.C. § 12203 and 29 CFR Parts 1630.12(a) and (b) and Parts 1630.13(b), (c), (d) and Part 1630.14(c).

**80.** Plaintiff incorporates the above statements of fact and the allegations contained in the paragraphs 1 through 48 herein and plaintiff's supporting affidavit which is also re-alleged and incorporated herein by reference.

**81.** In September of 2021, defendant began unceasingly to retaliate against plaintiff despite plaintiff's reasonable good faith belief that she was exercising protected opposition to discrimination and claiming rights protected under the ADA and ADA-AA.

**82.** The plaintiff was threatened to be terminated because of her unvaccinated condition and has successfully stated a violation of the Act simply because she has been subjected to an action prohibited under the law because of perceived physical impairment.

**83.** Defendant continued to threaten the plaintiff with suspension, dismissal, and termination even after plaintiff opposed the discrimination and was later made aware of a pending EEOC investigation and plaintiff's protected opposition status.

**84.** Defendant coerced plaintiff to submit to the accommodation measures, medical interventions and examinations and other health control measures, even though defendant was duly advised by plaintiff that she was not subject to any health control measures by any court order, and that the defendant was not empowered by any court order or other legal duty to impose such interventions, examinations or control measures upon plaintiff. [11]

11 See New York Public Health Legal Manual https://www.nycourts.gov/whatsnew/pdf/PublicHealthLegalManual.pdf

**85.** Defendant threatened plaintiff with the termination of employment then terminated her employment because of a perceived disability and as a result of classifying plaintiff as "unvaccinated".

**86.** Despite having knowledge of plaintiff claiming protected status under the ADA and ADA-AA, defendant terminated plaintiff's employment due to plaintiff's opposition to discriminatory policies and procedures.

**87.** Defendant also failed to give notice of plaintiff's right to refuse defendant's accommodations under the ADA and ADA-AA[12], and failed to advise plaintiff of her right to informed consent, thus interfering with the exercise of plaintiff's rights under the ADA and ADA-AA.

**88.** As a result of defendant's intentional, willful and unlawful acts of retaliating against plaintiff by terminating plaintiff's employment; interfering with plaintiff's right to informed consent; and interfering with plaintiff's right to refuse defendant's accommodations under the ADA and ADA-AA, plaintiff has suffered injury and damages.

**89.** The injury suffered by plaintiff is thereby concrete and particularized and it is actual and imminent. The injury alleged in the complaint, including the pleading and exhibits, clearly sets forth a set of facts that actually occurred and are not conjectural or hypothetical. The injury described therein is at least fairly traceable to the challenged action, conduct and policies of defendant.

**90.** The harm (injury) already suffered by plaintiff includes, but is not limited to, having to choose between waiving rights to: medical privacy, informed consent, refusal to take part in clinical trials, and be free of discrimination and retaliation OR having plaintiff's employment terminated. Once violated, these rights cannot be recovered.

**91.** Defendant's policies and procedures demonstrate soundly and convincingly that it intends to inflict future harm against plaintiff based upon perceived disability; it fully intends to continue these policies and it fully intends to continue retaliating against plaintiff as alleged herein.

12 29 CFR Part 1630.9 (d) & (e)

**92.** As a result of defendant's actions the plaintiff has experienced retaliation, coercion, interference, termination and disruption in plaintiff's career.

**93.** Defendant's efforts were to terminate plaintiff, rather than to provide equal access, per defendant's duty, and were not objectively or subjectively in good faith, therefore plaintiff is entitled to liquidated damages or other monetary damages, including punitive damages to the extent available.

**94.** **WHEREFORE**, Plaintiff respectfully requests entry of:

a. ordering defendant to comply with the requirements of Title I of the Americans with Disabilities Act, 42 U.S.C. §12101; and,

b. take such affirmative steps as may be necessary to prevent the recurrence of any retaliation, coercion, interference and intimidation and to eliminate, to the extent practicable, the effects of such conduct.

c. reinstatement, or, in the alternative, front pay in the event reinstatement is not practical;

d. judgment in plaintiff's favor and against defendant for actual and compensatory damages, including lost earnings, front pay, and/or all actual monetary losses suffered as a result of defendant's conduct;

e. judgment in plaintiff's favor and against defendant for plaintiff's reasonable court fees and litigation expenses;

f. judgment in plaintiff's favor and against defendant for punitive damages; and

g. assess a civil penalty against the defendant in an amount authorized by 42 U.S.C. §12101 to vindicate the public interest and make the plaintiff whole; and

h. an order granting such other and further relief as this Court deems just and equitable under the circumstances of this case.

**95.** Plaintiff demands a jury trial.

DATED this 8 day of June 2022.

Colleen Mone Plaintiff

Colleen Mone
Plaintiff in *Propria Persona*
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c.mone@aol.com

**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**
**225 Cadman Plaza East, Brooklyn, NY 11201**

COLLEEN MONE
PLAINTIFF

v. CASE NO._____

NEW YORK STATE UNIFIED
COURT SYSTEM
DEFENDANT
_____/

## AFFIDAVIT IN SUPPORT OF COMPLAINT

STATE OF NEW YORK )
) Ss
COUNTY OF RICHMOND )

1. I, Colleen Mone, do hereby solemnly affirm that the statements herein are true and correct in substance and in fact and that I have personal knowledge of each.

2. I have been harassed at my job, discriminated and retaliated against based on disability for refusing to accept my employer's accommodations for regarding me as impaired in my immune system and impaired in my respiratory system.

3. I am absent and without evidence of any information from any health officer identifying myself as having any communicable disease or having been exposed to any toxic substance.

4. I am absent and without knowledge of any evidence or court order, obtained by any petition of the Department of Health or a public health officer, that was based upon any physician's affidavit in which I have been identified as having any communicable disease or having been exposed to any toxic substance.

5. I am absent and without knowledge of any evidence of any court order determining that I am or have been a direct threat to anyone.

6. I am absent and without knowledge of any evidence of any individualized assessment required by law that has determined that I am or have been a direct threat to anyone.

7. I am absent and without knowledge of any evidence of any court order imposing any terms of isolation or quarantine or other measures upon myself.

8. I have previously and timely disclosed and duly noticed the defendant of a prior existing disability, and that the assertions made in the complaint are true and correct to the best of my knowledge, information and belief.

9. I have been employed as a Court Officer in the New York State Unified Court System for 16 years. On September 1, 2021, I received a Memo (Exhibit A-1) titled "Mandatory Testing Program" from Nancy Barry, Chief of Operations and Justin Barry Chief of Administration which makes clear that my employer regards me as disabled with an impaired immune system and an impaired respiratory system. My employer is requiring me to get "tested" for disease weekly on an on-going basis; and enter a record of the results on the UCS Sharepoint site. My employer is also coercing me to get injections under Emergency Use Authorization guidelines which necessarily have right of refusal. My employer wants to share my status regarding these mitigation measures with other employees via the UCS Employee web portal.

10. The Memo details harassing measures to be meted out by supervisors and threatens me with the retaliation of not being allowed to work if I do not submit to the new policy.

11. On September 8, 2021 I sent a letter (Exhibit A-2) to Lawrence Marks, Deputy Chief Judge dated September 7, 2021 in which I discussed the discrimination I am experiencing. I also mention that our Court Officers union needs to be included in any policy-making decisions.

12. On September 10, 2021 I received a "Vaccine mandate" memo (Exhibit A-3) from Nancy Barry, Chief of Operations and Justin Barry Chief of Administration which stated that I must be injected by September 27, 2021 or my job would be at risk and I would likely be fired. This memo shows that my employer regards me as impaired with the condition of being "unvaccinated" since it is threatening me with termination based upon its perception of me as impaired. In this memo my employer disregards my right to informed consent and this memo does not satisfy the requirement to disclose risk/benefit

analysis or acknowledge that I have the right to refuse an injection under EUA . My employer is responding to me as if I am a "Direct Threat" without relying on any medical diagnosis.

13. On September 15, 2021, I responded with an emailed letter (Exhibit A-4a) I titled "Employment Discrimination and Retaliation Based Upon Disability" which I addressed to Janet Difiore, Lawrence Marks, Justin Barry and Nancy Barry. I alerted the judges and administrators that I am experiencing discrimination based upon disability and I claimed my rights to informed consent and asked them to remediate themselves to the actual laws regarding due process in matters of Public Health and in Discrimination. This letter also let them know I am documenting the discrimination and I asked them to please review the NY Benchbook Guide compilation of Public Health laws and the due process they require in order to draw their attention to the requirement for an actual medical diagnosis before taking adverse employment actions. I also emailed a copy of this letter to my Union President Dennis Quirk. The USPS tracking shows the letters received at the court. (Exhibit A-4b)

14. The same day I contacted Human Resources with an emailed letter (Exhibit A-5a) I titled "Notice of Discrimination and Harassment based upon Disability" as a confidential communication to Carolyn Grimaldi and sent to Eva Moy in the Office of Managing Inspector General for Bias Matters (OMIGBM) to place in my file to document discrimination. I also sent this letter via certified mail to Grimaldi and the tracking shows she received it. (Exhibit A-5b)

15. I intended to officially give my employer notice that I am claiming and documenting discrimination and harassment I am receiving which is based upon it regarding me as having a disability. I asked both offices to create a file

for the purpose of documenting the discrimination, harassment and threatened retaliation I am experiencing.

16. On September 16, 2021 Carolyn Grimaldi Human Resources emails (Exhibit A-7) me and claims that she is not responsible for processing employee discrimination complaints and directs me to address Eva Moy, (OMIGBM) and my Union President of the Court Officers Association Dennis Quirk. I have already contacted both of them.

17. September 17, 2021, I asked Ms. Moy to give me the name of the designated employee who handles ADA cases. I received no response from her. Eva Moy never responded to me, although she did write my husband (Exhibit A-8) that the Inspector General's Office for Bias Matters has "no jurisdiction" for discrimination issues and she will not investigate claims of discrimination.

18. On September 20, 2021 I filed a Charge of Discrimination and Harassment (Exhibit A-9) with the EEOC via email and certified mail. The intake person is Hernan Morales (CRTIU Supervisor) and the ADR Supervisor is David Reinman for the New York District Office of the EEOC. I also sent a copy of this Charge to Eva Moy, OMIGBM; Carolyn Grimaldi, Human Resources and to the NY State EEOC Division of Human Rights.

19. The same day I emailed an "Amended" version of my "Notice of Discrimination and Harassment Based Upon Disability" (Exhibit A-10). Both Carolyn Grimaldi and Eva Moy have refused to process or investigate my complaint of discrimination. Grimaldi claimed she can't put my complaint in my "personnel" file, so I ask her to put my complaint in the appropriate file that can be accessed by the EEOC. Eva Moy told my husband that she does not have the "jurisdiction" to process a discrimination complaint, so I quoted the online

poster for the OMIGBM which states that Discrimination Complaints are exactly what her office handles. I ask her to review the poster information and I again ask her to process my complaint. I believe both these employees are interfering with my rights under the ADA by refusing to do an intake or investigate my claim.

20. On September 22, 2021 Carolyn Grimaldi emails me (exhibit A-11) that she is not to be included in any further correspondence on the matter of discrimination and the EEOC filing. I email her back asking who is the legal counsel for the Office of Court Administration.

21. On September 23, 2021, Grimaldi provides me the name and contact information for Kelvin Smartt who is an HR administrator and she gives me a phone number for the legal counsel for the Office of Court Administration.

22. On September 24, 2021 I email Kelvin Smartt everything that should go in my discrimination documentation file: copies of the EEOC Charge and my "Notice of Discrimination and Harassment Based Upon Disability". I sent him a copy of my Notice to Janet Difiore, Lawrence Marks, Justin Barry, and Nancy Barry. I let him know that Eva Moy has not responded to my latest request for her to process my discrimination complaint and that Grimaldi refuses further contact about this matter. Kelvin Smartt does not respond to me.

23. I have taken all the steps I can think of to notice my employer that it is regarding me as disabled with an impaired immune system and an impaired respiratory system, is discriminating against me, harassing me and threatening retaliation and other adverse employment actions. I have not had any agent for NYSUCS respond to me by actually doing an intake. All of these agents refuse to engage my concerns and refuse to assist me. They all have refused

to mitigate or even acknowledge the harassment and retaliation I am dealing with which increases my sense of isolation.

24. September 25, 2021, I am ordered to quarantine by my supervisor per office of court administration policy because I was in the same locker room as another co-worker who tested positive for COVID on September 24, 2021. I am told to quarantine until October 4, 2021 and return to work October 5, 2021.

25. On October 4, 2021 the New York State Court Officer Association sues and is granted a temporary restraining order effectively putting the Office of Court Administration's mandate on hold until a hearing on Thursday October 14, 2021.

26. October 18, 2021, I was handed a letter by Captain Robert Miglino claiming that I was "unfit to serve" as long as I was "unvaccinated" with the EUA injection. I was effectively terminated as of October 19, 2021. As there is no end-date when my employer will not consider my classification as "unvaccinated" as warranting an "unfit to serve" designation, I am terminated. I am also classified "non-compliant". I challenge both accusations by providing Captain Robert Miglino with a notice I titled "Invocation of Rights". In this document I state that I have the right of informed consent, the right of refusal under EUA and I claim my rights under the ADA. Therefore I do not need to comply with the policy; and I have answered every request for my responses in a timely fashion. I emailed copies of this notice to Janet Difiore, Lawrence Marks, Chief Michael Magliano, Justin Barry, Nancy Barry, Kelvin Smartt, and Eva Moy. No parties to date have responded to this notice. I also decided to send my Captain a daily email stating that I am fit for duty as long as I am barred from working.

27. October 28, 2021, I email Judy Keenan director of EEOC, that it has been over a month since I filed my Charge of Discrimination. I ask her to look into this matter and have someone assigned to my case.

28. October 29 – November 5, 2021, Ms. Lockett from the EEOC calls me. However, she was condescending and combative. She lectured me on when it was my turn to speak. I discontinued the conversation. The next day I reported Ms. Lockett's behavior to Judy Keenan. On the 5th of November I email Judy Keenan asking for a "Right to Sue" determination letter. I then received an email from Robert Rullan informing me that he sent my request for a Right to Sue letter without determination to the department of justice and they will be in contact via email. I received a Right to Sue Letter from the Department of Justice on December 7, 2021. (Exhibit A- 12)

29. The documents included with Exhibit A are true and correct copies of the originals.

Colleen Mone, Affiant

STATE OF NEW YORK )
Ss
COUNTY OF RICHMOND )

Subscribed and sworn to before me a notary public this 9th day of December, 2021.

Signature of Notary [ls]

GINA ERVOLINO
NOTARY PUBLIC STATE OF NEW YORK
RICHMOND COUNTY
LIC. #01ER6157213
COMM. EXP. 12/4/22

EXHIBIT A

written communications

EXHIBIT B

Guidance for Industry and FDA

Exhibit C

Employment Contract

Unified Court System
OFFICE OF COURT ADMINISTRATION

LAWRENCE K. MARKS
CHIEF ADMINISTRATIVE JUDGE

NANCY J. BARRY, ESQ.
CHIEF OF OPERATIONS

JUSTIN A. BARRY, ESQ.
CHIEF OF ADMINISTRATION

# MEMORANDUM

September 1, 2021

To: All Judges and Non-Judicial Staff

From: Nancy J. Barry
Justin Barry

Re: Mandatory Testing Program – Supplemental Information

---

As announced last month, the Unified Court System will begin its mandatory COVID-19 testing program on September 7, 2021. Fully vaccinated judges and nonjudicial employees, who have submitted proof of vaccination *via* the Revised Mask Policy ("Orange Card") Program will be exempt from this testing program.

As promised, this memorandum will offer detailed information on how judges and employees will submit proof of testing and supplemental information on other aspects of the program.

A copy of the August 18, 2021 memorandum is attached for your information.

**Mandatory Testing Procedure**

1. Exemption

   To be exempt from weekly testing, judges and nonjudicial employees must submit proof of full vaccination using the UCS share point site – https://nycourts.sharepoint.com/sites/COVID-19/CPV. Individuals uploading proof of vaccination may now select whether they wish to be issued an orange card. The share point site will email confirmation to the applicant when the proof of vaccination is submitted and when it has been approved. Judges and nonjudicial employees must submit proof of fully vaccinated status by the close of business on September 3, 2021. Any judge or nonjudicial employee who has not received an email confirming that their proof of vaccination has been approved by the close of business on September 7, 2021 will be required to begin weekly COVID-19 testing the week of September 13, 2021, as explained further below.



25 BEAVER STREET, NEW YORK, NEW YORK 10004 • PHONE: 212-428-2120 • FAX: 212-428-2190

Nonjudicial employees that received paid leave and/or Compensatory Time ("CT") for attending vaccination appointments are still required to upload proof of fully vaccinated status through the share point site in order to be exempt from weekly testing. Under no circumstances will employees who received paid leave and/or CT for attending vaccination appointments be granted paid leave for purposes of weekly testing.

2. Start of Testing Program

The weekly testing program starts on September 7, 2021. On September 7, 2021 every Kronos supervisor, Administrative Judge and Supervising Judge ("supervisor") will receive an email with a link to the UCS Employee Web Portal ("Portal") which will contain a list of all of the judges or employees ("participants") under their supervision who must submit weekly proof of COVID tests. (Again, judges and nonjudicial employees who have submitted an approved proof of vaccination will be excluded from this list).

While participants will not be required to submit proof of testing during the week of September 7, 2021, they should use this time to coordinate a time with their supervisor to be tested during their regular work hours in the workweek that follows, i.e. the week starting September 13, 2021. Nonjudicial employees will be provided with one (1) hour of paid leave without charge to accruals each week for purposes of undergoing this testing.

Participants must upload proof of testing within one workday from the day they were tested. Supervisors will need to check the Portal each workday to ensure each participant has timely submitted proof of testing.

3. Supervisor Scheduling

Supervisors will be responsible for ensuring that all participants on their September 7, 2021 "Portal" list have coordinated/scheduled a date and time to undergo testing during the week that follows.

To the extent practicable, and subject to the operational needs of the court and the availability of testing appointments, the supervisor and participant may want to coordinate/schedule a set day and time each week for the participant to undergo testing, i.e., establish a recurring testing hour each week. Supervisors should be flexible, where possible, to accommodate a participant's scheduled or unscheduled leave or available testing appointments.

Nonjudicial employees are entitled to one (1) hour of excused leave per week which will be granted upon substantiating that testing was conducted on the date the employee was released from work for their test. Supervisors will make every effort to coordinate/ schedule release time at a mutually convenient time, taking into consideration that some

employees may wish to be tested at a location near their home while others may find it easier to be tested near their workplace.

In order to ensure adequate release time, participants should make every effort to schedule and/or request their one-hour of excused leave with their supervisor by the Wednesday preceding each testing week, e.g., by Wednesday, September 8, 2021 for testing the following week. Supervisors should note and/or keep track of each participant's scheduled hour (by calendar or some other method) that will allow them to confirm that the participant is released for testing and that proof of testing is timely uploaded thereafter.

Nonjudicial employees that are overtime eligible, i.e., required to swipe in/out at the beginning and end of their shift should follow the normal rules for appointments during the workday. That is, only if the employee is not expected to return to work following their test are they required to swipe out, e.g., an overtime eligible employee with regular hours of 9:00 AM to 5:00 PM that is scheduled for a 4:00 PM test is not expected to return to work and therefore, must swipe out when leaving for their test/appointment.

4. Submitting Proof of Test

Upon completion of the test, each participant should be sure to obtain an electronic confirmation (pdf or jpeg) or paper document from the testing facility indicating that they took the test with the date, time, location and facility information. The participant must upload a copy of that confirmation using the Portal, which is accessible anywhere from any device using the following URL - https://portal.nycourts.gov/ucsmtp/.

Upon clicking the Portal URL, the participant will be asked for their UCS user id and password (same user id and password used for Kronos and Outlook) and the date and time of their test for that week. At the bottom of the Portal page, the participant will upload a digital image of their proof of test which must include the location, date, time and type of test.[1]

Instructions for using the Portal in every operating system are contained on the Portal upload page. Nonjudicial employees that do not have regular access to a UCS computer and do not wish to use their personal mobile device to upload proof of testing may request access to a computer at their worksite from their supervisor.

---

[1] Acceptable tests include PCR, RT-PCR, ddPCR, Rapid PCR (Polymerase Chain Reaction), NAA / NAAT (Nucleic Acid Amplification), AMP PRB (Amplified Probe), LAMP (Loop-mediated Isothermal Amplification), TMA (Transcription-mediated Amplification). Molecular test brands, such as, but not limited to: Abbott ID NOW, Quidel Lyra PCR, Abbott Realtime PCR, Cobas Qualitative PCR, FTD PCR, Xpert Xpress and Simplexa Direct PCR.

Unacceptable tests include all Antigen (Ag) tests (including Quidel Sophia, Abbott BinaxNOW and Rapid Antigen Tests), all Antibody tests (such as IgG, IgA, IgM and Rapid Antibody Tests), all blood tests (such as fingerstick, venipuncture), all plasma tests, all serum tests and all lateral flow tests.

5. Supervisor Review

Each morning at 10:00 AM, supervisors will receive a combined COVID Self-Assessment and COVID Test Advisory email with a link. The link will take the supervisor to the Portal which will indicate which participants have completed their daily self-assessment and which participants uploaded their proof of test on the previous day.

The supervisor should then compare their participants' schedule of tests for that week to ensure the participants have completed the test as scheduled.

If a participant does not submit a proof of test within one workday of the scheduled hour for that week but reports a valid reason why he/she was unable to submit his/her proof of testing (e.g., the pharmacy canceled their appointment, there was technical trouble uploading the proof, they were sick on the day of the appointment), the supervisor should exercise reasonable discretion in permitting the participant an additional opportunity to be tested and/or upload proof of testing during that workweek.

If the employee does not present mitigating circumstances and/or refuses to comply, the matter must be referred to the District Executive or NYC Chief Clerk, who should exclude the employee from the workplace for their failure to comply with the testing program. As is the case with employees who do not comply with UCS screening and/or self-assessment protocols, employees that are excluded from the workplace for failure to comply with the testing program may be considered absent without authorization for which approval to charge accruals may be denied.

6. Additional Information

Participants can find locations, times and descriptions of testing sites at https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html or https://coronavirus.health.ny.gov/find-test-site-near-you. Testing sites are widely available and many are free of charge. It is the responsibility of each participant to find a location near their home or workplace and schedule their testing time with their supervisor.

As the testing program is rolled out in September, employees should bring any concerns or difficulties that they face regarding testing to their supervisor, who will in turn forward them to the appropriate District Executive or NYC Chief Clerk. The District Executive and NYC Chief Clerks will collect any concerns or difficulties experienced in their District or Court and refer them to the appropriate Deputy Chief Administrative Judge ("DCAJ"). The DCAJ should forward all such concerns or difficulties to OCA Human Resources for further review/consideration.

cc: Hon. Lawrence Marks
Hon. George Silver
Hon. Edwina Mendelson
Hon. Norman St. George
Administrative Judges
NYC Chief Clerks
District Executives
OCA Directors
Chief Michael Magliano

From: c.mone@aol.com,
To: lmarks@nycourts.gov,
**Subject:** Honorable Lawrence Marks
**Date:** Wed, Sep 8, 2021 6:00 am

Honorable Lawrence Marks, September 8, 2021

The following statement addresses the office of court administration's new mandatory covid testing policy slated to begin September 7, 2021. Judge Difiore has repeatedly claimed that the office of court administration is following CDC guidelines. According to CDC data, vaccinated individuals can contract and transmit covid just as readily as unvaccinated do. As a matter of fact, vaccinated employees are testing positive in the courts everyday. If this policy has been put in place to ensure the safety of all employees, and also in accordance with the CDC's current guidelines, it would call for the testing of all employees indiscriminately. The policy states that the office of court administration will only test employees who are either unvaccinated or unwilling to disclose their medical status. If the office of court administration moves forward with mandatory testing only of employees not enrolled in their orange card program it is extremely biased and discriminatory. Forcing healthy employees, absent any symptoms to be tested is implicitly unjust. The one hour time constraint that the office of court administration mandated for testing adds an additional layer of undue stress, not only on employees, but also on court operations. According to the office of court administration's mandatory testing policy if a healthy employee refuses to test weekly the office of court administration intends to forcefully send that employee home unfit to serve, label that employee absent without authorization, and possibly withhold pay. This is punitive and retaliatory. Will the court of administration be requiring attorney's or members of the public to provide proof of a weekly covid test? On February 5, 2021 Judge Difiore was quoted as saying "any case involving claims of discriminatory conduct would necessitate a full disciplinary hearing ". Plain and simple, this is discrimination and requires an Anti-Discrimination panel. We feel the office of court administration are required to have our concerns of discrimination against us heard through a formal hearing.

The following addresses the court of administration's unconstitutional vaccine mandate slated to begin September 27, 2021. First and foremost the office of court administration's refusal to negotiate with its employees union representation is prejudicial. We pay union dues and are unable to be fairly represented. Mandating a vaccine under the threat of termination lacks empathy. Taking away an employee's bodily autonomy under the guise of public safety is morally offensive. The vaers reporting system has over 50,000 adverse effects from receiving the vaccine. Will the office of court administration be held liable for injuries or death? Where is the office of court administration's consideration of natural immunity? It is already September 8, and we have no instructions on how to apply for medical or religious exemptions. How are employees expected to have time to schedule appointments with their doctors or spiritual advisors if that is the route they so desire? Sending home employees as unfit to serve, who are in good standing and regularly report to work as scheduled is absurd. Have you considered the stress you are putting on your employees disregarding their free will with the threat of termination? Both of these mandates are discriminatory. Since the chief judge refuses to negotiate with our union leadership we are appealing to you Judge Marks, we urge you to reverse course on this unlawful policy.
We appreciate the office of court administration's immediate attention to this matter

Thank you
Christopher Mone
Court Officer Richmond Family

This statement is supported by many court employees including the following:
Colleen Mone, Michael Mallen, Kerri Beyers, Robert Lavanco, Matt Joseph, Joe Colasuonno, Peter Scalfani, Andrew Park, Michael Decicco, Michael Williams, Gina Ervolino, Andrea Stefanski, Alex Rivera, Jason

Sent from my Verizon, Samsung Galaxy smartphone

Unified Court System
OFFICE OF COURT ADMINISTRATION

LAWRENCE K. MARKS
CHIEF ADMINISTRATIVE JUDGE

NANCY J. BARRY, ESQ.
CHIEF OF OPERATIONS

JUSTIN A. BARRY, ESQ.
CHIEF OF ADMINISTRATION

# MEMORANDUM

September 10, 2021

To: All Non-Judicial Personnel

From: Nancy J. Barry
Justin Barry

Re: Mandatory Vaccination Requirement

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As previously announced, the Unified Court System will require all judges and non-judicial personnel to be vaccinated by September 27, 2021, unless otherwise approved for an exemption due to medical reasons or sincerely held religious beliefs, as explained more fully below.

This memorandum will outline the program as it relates to non-judicial personnel. The Chief Administrative Judge will outline the program for judges in a separate document.

**Proof of Vaccination**

All non-judicial personnel must be fully vaccinated against COVID-19 by September 27, 2021, or as soon thereafter as medically practicable provided they have received at least one dose of a COVID-19 vaccine by such date.[1]

To this end, no later than September 27, 2021, all non-judicial personnel must either submit proof that they: (1) are fully vaccinated; or (2) have received at least one dose of any COVID-19 vaccine. This proof must be submitted through the UCS SharePoint site https://nycourts.sharepoint.com/sites/COVID-19/CPV as outlined in Section (1) of our September 1, 2021 Memorandum (Mandatory Testing Program – Supplemental Information).

[1] Fully vaccinated is defined as: two weeks after receiving a second dose of a two-dose vaccine, such as the Pfizer or Moderna vaccines; or two weeks after receiving a single-dose vaccine, such as the Johnson and Johnson vaccine.

Acceptable proof of having received at least one dose of a COVID-19 vaccine is a copy of the front **and** back of the employee's vaccination card. For fully vaccinated employees, a screenshot of the employee's Excelsior Pass is also acceptable. Those employees, who submit proof of having received their first dose of a two-dose vaccine, will be required to submit proof of having received the second dose within the medically recommended timeframe, i.e., typically 3 weeks from the first dose, using the same UCS SharePoint site referenced above.

Employees, who have submitted proof of vaccination by September 27, 2021 but are not yet fully vaccinated because they must receive a second dose and/or they must wait an additional two weeks after their last dose, will be subject to the Mandatory Testing Program until such time as they are fully vaccinated.

**Exemptions**

Exemptions to the mandatory vaccination requirement will be considered for employees with underlying medical conditions that make receiving the COVID-19 vaccine unsafe for them and employees with sincerely held religious beliefs and practices that prohibit them from receiving a COVID-19 vaccine.

Employees seeking a medical or religious exemption to vaccination must submit their request by 5:00 p.m. on September 27, 2021 using the appropriate exemption form (see attached Exhibit A – Medical Exemption Request Form and Exhibit B – Religious Exemption Request Form). The completed Exemption Request Form must be scanned and uploaded through the UCS Employee Web Portal located at https://portal.nycourts.gov/ExemptionCOVID19Vaccination/. Instructions for uploading these Forms will be available on the Portal, which will "go live" on September 20, 2021.

No exemption requests will be considered unless they are fully completed on the appropriate form and filed through the Portal.

Applications for medical exemptions must be accompanied by documentation from the employee's medical health professional. Applications for religious exemption must contain the employee's written, signed and notarized statement detailing the religious basis for his/her objection to COVID-19 vaccination and the religious principle(s) that guide the objections to COVID-19 vaccination. Employees submitting an exemption application will be notified, in writing, of the decision [which, if granted, will include the expiration date of the exemption] or, that more information is needed in order to consider the employee's request for an exemption, as soon as practicable after their request is filed.

Employees who timely file a request for exemption will be subject to the Mandatory Testing Program while their request is being reviewed. Those employees who are granted a medical or religious exemption to vaccination will be subject to the Mandatory Testing Program during the specified exemption period.

An employee who receives written notice that their request for medical or religious exemption was denied will have ten workdays from the date of the notification to submit proof of having received

at least one dose of a COVID-19 vaccine and must otherwise comply with the provisions set forth in "Proof of Vaccination" above.

**Non-Compliance**

Employees who fail to comply with the provisions of this Policy are prohibited from reporting to work and may be considered absent without authorization for which approval to charge accruals may be denied, until they have taken steps to remedy their non-compliance. Continued failure to comply may result in disciplinary action, up to and including termination.

**Additional Information**

Non-judicial personnel are reminded that they are eligible for Excused Leave and/or Compensatory Time for becoming vaccinated (up to 3.5 hours per appointment upon submission of the requisite proof of same).

Non-judicial personnel must continue to follow all other safety and operational protocols.

We are deeply grateful to our staff for their collaboration in the ever-evolving guidance surrounding COVID-19 and their commitment to keeping themselves, their colleagues and all who conduct business in our facilities safe.

cc: Hon. Lawrence Marks
Hon. George Silver
Hon. Edwina Mendelson
Hon. Norman St. George
Administrative Judges
NYC Chief Clerks
District Executives
OCA Directors
Chief Michael Magliano

Colleen Mone
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Janet Difiore, Chief Judge
Jdifiore@nycourts.gov
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Nancy J. Barry, Chief of Operations
nbarry@nycourts.gov
646-386-4600

Justin A. Barry, Chief of Administration
jbarry@nycourts.gov
646-386-4600

Lawrence K. Marks, Chief Administrative Judge
Lmarks@nycourts.gov
212-428-2884

CONFIDENTIAL COMMUNICATION
29 CFR §1630.14(c)(1)
September 10th 2021.
RE employment discrimination and retaliation based on disability
Greetings,

Each of you must be aware by now that your (New York State Unified Court System) Covid-19 policies to impose medical interventions such as mask-wearing, testing and experimental drugs including the vaccinations are patently illegal. You are the people that know better and of which a higher degree of understanding and conduct is incumbent upon you, yet you are participating in these discriminatory policies in spite of your expertise and professional obligations.

Be advised that in spite of your ignoring my first complaints over this matter, I am continuing to document your violations of the law and discrimination based upon disability by opening a confidential file with human resources. I intend to make this a matter of public record by filing a complaint against the court for its violations of Title I of the Americans with Disabilities Act.

I'm not required to take experimental drugs as a condition of my employment and I've never waived my rights to medical privacy or informed consent. No matter what your professional standing and whether or not there is any pandemic, no laws have changed and I have never waived any of my medical privacy rights. Judges and attorneys of all people should know this, as I'm sure you are aware that it is a crime to falsify government and court records as you are now doing in contumacious disregard for the law.

You are not permitted to regard me as having a disability, then make a record of such disability and then compel me to submit to your medical interventions without my consent. Please be advised of the law, Title I of the Americans with Disabilities Act, 29 CFR Part 1630.9(d). No laws have changed, you already know this. You have no greater duty of care, in fact, you are violating your duty of care.

You each need to remediate yourselves of the actual laws of the State of New York as compiled and published in the New York State Public Health Manual, A Guide for Judges, Attorneys and Public Health Professionals and the Americans with Disabilities Act.

Sincerely,
Colleen Mone

Complete items 1, 2, and 3.
Print your name and address on the reverse so that we can return the card to you.
Attach this card to the back of the mailpiece, or on the front if space permits.

Article Addressed to:

DIFIORE, L. MARKS
BORRY, J. BARRY
5 Beaver St
New York NY 10004

9590 9402 6934 1104 5517 17

Article Number (Transfer from service label)
7020 3160 0001 2670 7543

X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) COVID-19 C. Date of Delivery 9-15-21

D. Is delivery address different from Item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☐ Adult Signature
☐ Adult Signature Restricted Delivery
☒ Certified Mail®
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☐ Collect on Delivery
☐ Collect on Delivery Restricted Delivery
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☐ Registered Mail™
☐ Registered Mail Restricted Delivery
☐ Signature Confirmation™
☐ Signature Confirmation Restricted Delivery
☐ Restricted Delivery (over $500)

Form 3811, July 2020 PSN 7530-02-000-9053 Domestic Return Receipt

Colleen Mone
c.mone@aol.com

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Carolyn Grimaldi, Human Resources
New York State Unified Court System
212-428-2884
Cgrima11@nycourts.gov
CONFIDENTIAL COMMUNICATION
29 CFR §1630.14(c)(1)
September 10th 2021.
RE employment discrimination based on disability
Ms Grimaldi,

My first complaint of this nature was ignored, but I have documented the correspondence and I'm advising you to respond this time. This is a confidential communication that I am requesting be included into my personnel file and I want this and subsequent communications to be kept confidential within human resources. I'm documenting acts of discrimination based upon disability, intimidation, retaliation and harassment by Janet Difiore, Nancy J. Barry, Justin A. Barry and Lawrence K. Marks, of which I have been subjected to on-the-job. I also want to speak confidentially to the court's designated employee or representative for matters involving grievances under Title I of the Americans with Disabilities Act as it pertains to on-the-job discrimination and retaliation based upon disability.

The court and these employees regards me as having a disability (contagious disease) without any diagnosis or individualized assessment and has also made a record of such disability by mis-classifying me as having, a mental or physical impairment that substantially limits one or more major life activities.

Please explain why the court and its employees are discriminating against me based upon a disability that the court and its employees are regarding me as having, and the reason why the court has made and continues to make a record of such disability? I am invoking my rights under Title I of the Americans with Disabilities Act as a qualified individual with a disability.

I am being regarded as having a contagious disease without any individualized assessment and continually being asked for my medical records and to submit to medical examinations and interventions (accommodation measures) without any informed consent. It has been extremely difficult to perform my employment duties because of these interruptions and harassment.

Regarding the accommodation measures described in the court's memorandum and administrative order dated September 1st 2021, its website at https://www.nycourts.gov/ and related communications, please be advised that I am not required to accept these or any accommodations under Title I of the ADA, 29 CFR Part 1630.9(d). Moreover, I am not required to prove any "exemption" but you alone have the burden of proving that I am a direct threat. I demand to review the records you have relied upon to determine that I am a direct threat. If you have some legal authority that overrides this, please provide me with a legal citation.

Be advised that 29 CFR Part 1630 prohibits state agencies (employers) from requiring medical examinations or making disability-related inquiries of employees unless such

examination or inquiry is shown to be job-related and consistent with business necessity under 42 U.S.C. §12112(d)(4); 29 CFR §1630.14(c)

My questions are:

1. Why do you regard me as having a disability and what records have you made of this?

2. What physician, what medical records, and what complaint made by a physician to a health officer, and "orders of isolation and quarantine" do you rely upon for diagnosing me as having a contagious disease? Please include all, evidence, court records and records from the individualized assessment used in making this determination or diagnosis as required under Title I of the Americans with Disabilities Act.

3. Please identify the statute and regulation imposing your legal duty of care that requires you to protect me and others from any contagious disease.

4. Please provide a copy of documentary evidence from the departments of health or labor establishing the existence of a disease that has been isolated by modern scientific standards and documentary evidence proving that such disease is airborne, deadly and contagious.

5. Please identify your insurable risk with a copy of your insurance binder showing that you are insured for protecting employees from a contagious disease, and any adverse health consequences they may suffer as a result of your accommodation measures.

6. Regarding the accommodation measures, a) why have you refused to include notice that these are made under an emergency use authorization period, and refused to disclose the risks and benefits of the product, and also advise me of my right to either accept or refuse the product, and b) which of these accommodation measures has the proven efficacy to prevent transmission or infection of the contagious disease for which you regard me as having?

7. How are your requests for my medical information and submitting to medical examinations and interventions necessary for the performance of my employment duties?

8. Why are you able to diagnose me with a deadly disease and impose restrictions and medical interventions without my informed consent, without any physician's oversight or judicial approval, yet I am required to obtain written permission from my physician to exercise my rights to informed consent and medical privacy? We can stipulate that I have never waived any of my rights to medical privacy which includes the right of informed consent as a condition for employment.

9. Please disclose records of the court's budget approval for using public funds for administering or prescribing health control measures without judicial oversight and approval, without any licensing, insurance or medical training and without the supervision of any physician.

Please identify the designated employee responsible for resolving matters concerning on- the-job discrimination based upon disability.

Be advised that it is illegal to condition my employment upon submitting to your accommodation measures, this constitutes discrimination based upon disability, a violation of 29 CFR Part 1630, for which I would have a claim for employment discrimination based upon disability.

Sincerely,
Colleen Mone

Complete items 1, 2, and 3.
Print your name and address on the reverse so that we can return the card to you.
Attach this card to the back of the mailpiece, or on the front if space permits.

Article Addressed to:

CAROLYN GRIMALDI
15 BEEKMAN ST
NEW YORK, NY, 10004

9590 9402 6934 1104 5518 23

Article Number (Transfer from service label)
7020 3160 0001 2670 7529

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) COVINS-LY

C. Date of Delivery 9.15.21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☐ Adult Signature
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☐ Registered Mail™
☐ Registered Mail Restricted Delivery
☐ Signature Confirmation™
☐ Signature Confirmation Restricted Delivery

Form 3811, July 2020 PSN 7530-02-000-9053 Domestic Return Receipt

**To:** cmone@aol.com,
**Subject:** September 10, 2021 Letter Re: Employment Discrimination Based on Disability
**Date:** Thu, Sep 16, 2021 4:37 pm

Dear Ms. Mone,

I'm in receipt of your letter dated September 10, 2021, transmitted to me in duplicate via regular mail and certified mail [received today], which appears to be the same letter sent to me by Christopher Mone via email, regular mail and certified mail, including but not limited to the email address to which I'm directing this response.

Please be advised that your Personnel File is not maintained by the Division of Human Resources -- rather, it is maintained locally in the Administrative Office for your Court.

Nonetheless, an employee's Personnel File may only contain authorized records documenting the employee's work history, conduct and/or work performance such as: resumes or applications; appointment letters; probationary term notifications; statements of receipt of employee handbook, discrimination claim policy, sexual harassment policy, etc.; declination to participate in sick leave bank program; receipts for keys and other custodial items; documents relating to professional development programs, diplomas and certificates; applications for leave; performance evaluations; counseling memoranda; disciplinary records; grievances and resulting step decisions; reports of work-related injuries; requests for reassignment; requests for reclassification, military orders; and resignation and terminations letters.

Specifically prohibited from placement in an employee's Personnel File are: any documents or records pertaining to confidential medical and/or health information [including any back-up medical related to leaves of absence]; **complaints filed pursuant to Discrimination Claim Procedures** or Sexual Harassment Policy; complaints filed pursuant to State or Federal Occupation Safety and Health Acts; letters from creditors or letters of garnishment; background screening; and financial disclosures documents.

Based on the foregoing, the request for your September 10, 2021 letter "RE: employment discrimination based on disability" to be placed in your Personnel Folder must be denied. However, as I am mandated to report complaints of harassment and/or discrimination to the Office of the Inspector General [which is charged with maintaining documents and records pertaining to such claims], I have forwarded your letter to that Office for review and processing as it deems necessary and appropriate.

Questions or concerns about the Court System's Vaccination and/or Testing Policies should be referred to your Union.

Regards,

Director of Human Resources

Office of Court Administration

25 Beaver Street, 7th Floor

New York, NY 10004

Tel: (212) 428-2515

From: MIGBM@nycourts.gov,
To: c.mone@aol.com,
**Subject:** RE: I am sharing '1_5039861775000928585' with you
**Date:** Fri, Sep 17, 2021 2:53 pm

---

Chris Mone, the Office of the Managing Inspector General for Bias Matters is in receipt of your email.

However, based on the facts presented in your complaint, we do not have jurisdiction to investigate this matter.

Thank you.

**From:** c.mone <c.mone@aol.com>
**Sent:** Wednesday, September 15, 2021 4:19 PM
**To:** MIGBM <MIGBM@nycourts.gov>
**Subject:** FW: I am sharing '1_5039861775000928585' with you

Ms Moy,

This is a confidential communication sent to Janet Difiore, Lawrence Marks, Justin Barry, and Nancy Barry. To date all named parties have regretfully ignored it.

I am documenting the office of court administration's behavior on this and all other matters.

Thank you

Chris Mone

Sent from my Verizon, Samsung Galaxy smartphone

-------- Original message --------

From: "c.mone" <c.mone@aol.com>

Date: 9/12/21 11:05 PM (GMT-05:00)

Colleen Mone
83 Windsor Road
Staten Island, New York 10314
c.mone@aol.com

| | |
|---|---|
| David L. Reinman, ADR Coordinator<br>New York District Office EEOC<br>33 Whitehall Street, 5th Floor<br>New York, NY 10004<br><br>david.reinman@eeoc.gov<br>929-506-5306 | CRTIU Supervisor<br>New York District Office EEOC<br>33 Whitehall Street, 5th Floor<br>New York, NY 10004 |
| Eva Moy, OMIGBM<br>Office of Court Administration<br>25 Beaver Street<br>New York, New York 10004<br><br>Phone: (646) 386-3507<br>email: migbm@nycourts.gov | New York State EEOC<br>Division of Human Rights<br>complaints@dhr.ny.gov |

September 20, 2021

**For New York District Office EEOC**

# Charge of Discrimination
# and
# Request for Investigation and Mediation

## STATEMENT IN SUPPORT OF COMPLAINT

I am making this complaint against my employer for its discrimination against me based upon disability. The name and address of my employer is: New York State Unified Court System, 25 Beaver Street, New York, New York 10004. The EEOC has the authority and legal duty investigate this complaint.

My employer regards me as having a disability: a contagious disease.

My employer has made a record of such disability.

My employer has failed to conduct any individualized assessment to determine if I am a direct threat to anyone. My employer has failed to engage in any interactive process with me concerning disability rights or resolutions.

Witness List:

1. Janet Difiore, Chief Judge, Jdifiore@nycourts.gov
2. Nancy J. Barry, Chief of Operations, nbarry@nycourts.gov
3. Justin A. Barry, Chief of Administration, 646-386-4600, jbarry@nycourts.gov
4. Lawrence K. Marks, Chief Administrative Judge, Lmarks@nycourts.gov
5. Carolyn Grimaldi,Director of Human Resources grima11@nycourts.gov
6. Eva Moy, The Managing Inspector General for Bias Matters migbm@nycourts.gov
7. Dennis Quirk, President New York State Court Officers Association nyscoa@aol.com

I have asked to speak confidentially with my employer's designated employee or representative that is responsible for resolving matters involving the Americans with Disabilities Act and grievances thereunder, but my employer refuses to provide me access to such a person.

Instead, my employer has offered various accommodation measures including but not limited to mask-wearing, staying six feet away from others, frequent hand-washing, collection, use and storage of my vital statistics, histological samples and biometric data and biometric identifiers without adequate or proper notice, adequate disclosures, adequate data retention security or my informed consent, working in isolation, video-graphic and audio-graphic communications in lieu of face to face communications, working behind clear shielding, and injections of certain types of suspensions which are being called "vaccinations" yet do not prevent infection or transmission of any contagious disease and in fact create more disabilities by altering the normal function of my immune system and other cellular functions. My employer has not merely "offered" such accommodation measures, but threatened me with penalties including those described herein for refusing such accommodations in violation of 29 CFR Part 1630.9(d).

I then informed my employer that I do not accept such "accommodations" because I have not requested any accommodation and because I am a qualified individual with a disability that substantially limits my ability to engage in one or more major life activities.

My employer asked me to describe my disability and discuss it with certain employees, even though such disability does not adversely affect my ability to perform the duties of my employment, and has done so without any offer or attempt to make such disclosures in confidence or privately.

I have requested information regarding the risks and benefits of my employers accommodation measures and in response, my employer has retaliated against me by humiliating me in front of others, by reprimanding me and has threatened or intimidated or

coerced me with the threat of suspension of my pay, reduced hours or pay or the termination of my employment for refusing such accommodation measures instead of providing me with the information I requested so that I could make an informed decision.

I have exercised my right to refuse such accommodation measures and proposed instead that I be permitted to perform my employment duties without harassment, retaliation, coercion or intimidation as a result of my exercise of such rights, and my employer has prevented and interfered with this occurring.

I have not requested reasonable modifications but only that I be permitted to perform my employment duties without harassment, retaliation, coercion or intimidation.

My employer has instead retaliated against me for exercising my rights under the Americans with Disabilities Act by threatening me with disciplinary measures and penalties for refusing such accommodation measures, including but not limited to suspension or reduction of pay, limiting my access to the premises where I work, segregation, isolation, termination of employment, exclusion from programs or services that would permit me to improve my employment skills or become eligible for advancement, and denied me the possibility for promotion even when I was eligible or would become eligible.

Each day my employer permits and encourages other employees, including my supervisor and managers to harass and intimidate me and ask me for medical, health and other personal information that does not pertain to, or is not necessary for, the performance of my employment duties.

I am thereby being denied equal access to the same programs, activities, benefits, jobs or other opportunities for which I am otherwise qualified, while other employees are not. I am being segregated, excluded and relegated to lesser services by my employer based solely upon disability.

My employer has written and adopted policies that exacerbate my disabilities and create disabilities while also encouraging others to retaliate against me for exercising my rights under the Americans with Disabilities Act.

My employer has failed or refused to fulfill its duty to aid and encourage me in the exercise of my rights which are protected under the Americans with Disabilities Act.

My employer has demonstrated by the actions of its employees and by its own written policies that it intends to continue such violations and failures to comply with the law and violation my rights.

**REQUEST FOR INVESTIGATION AND MEDIATION**

By filing this Charge, I am formally requesting an investigation and mediation hearing to resolve these issues. I request that my Charge be entered manually and a hearing be scheduled. I request the CRTIU Supervisor to enter my Charge into the EEOC system personally as I do not find the online portal acceptable or accessible for entering my

Charge. I request a written response from the CRTIU Supervisor confirming that my Charge has been filed within 14 business days of receipt of this Notice.

Colleen Mone

Enclosure Copies:

1.) Notice of Employment Discrimination & Harassment Based on Disability

Colleen Mone
c.mone@aol.com

| | |
|---|---|
| Carolyn Grimaldi, Human Resources<br>New York State Unified Court System<br>212-428-2884<br>Cgrima11@nycourts.gov | Eva Moy, Office of the Managing Inspector General for Bias Matters<br>Office of Court Administration<br>Phone: (646) 386-3507<br>migbm@nycourts.gov |

**CONFIDENTIAL COMMUNICATION**
29 CFR §1630.14(c)(1)

September 20, 2021

RE: Amended Notice of Employment Discrimination Based on Disability

Hello Ms. Grimaldi and Ms. Moy,

This is a confidential communication that I am requesting Carolyn Grimaldi to include in the appropriate personnel file for complaints of discrimination which the EEOC can access and I want this and subsequent communications to be kept confidential within human resources and the OMIGBM. I'm documenting acts of discrimination based upon disability, intimidation, retaliation and harassment by Janet Difiore, Nancy J. Barry, Justin A. Barry and Lawrence K. Marks, of which I have been subjected to on-the-job. I also want to speak confidentially to the court's designated employee or representative for matters involving grievances under Title I of the Americans with Disabilities Act as it pertains to on-the-job discrimination and retaliation based upon disability who I believe is Eva Moy.

I understand that The Office of the MIG for Bias Matters conducts confidential investigations in connection with allegations of discrimination and bias that affect the conditions and terms of employment, or that relate to services provided by court system personnel. I request Eva Moy to open a complaint and investigation on my behalf regarding on-going discrimination, harassment and retaliation I am experiencing by my employer.

I am documenting that the court and these employees are regarding me as having a disability (contagious disease) **without any diagnosis or individualized assessment** and have also made a record of such disability by **mis-classifying me** as having, a mental or physical impairment that substantially limits one or more major life activities.[1]

I wish to open a complaint and have an investigation determine why the court and its employees are discriminating against me based upon a disability that the court and its employees are regarding me as having, and why the court has made and continues to make a record of such disability? I am invoking my rights under Title I of the Americans with Disabilities Act as a qualified individual with a disability.

I am being regarded as having a contagious disease without any individualized assessment and continually being asked for my medical records and to submit to medical examinations and interventions (accommodation measures) without any informed consent. It has

1 This behavior is also symptomatic of a mental illness known as Factitious Disorder (DSM, 5th Ed.)

been extremely difficult to perform my employment duties because of these interruptions and harassment.

Regarding the accommodation measures described in the court's memorandum and administrative order dated September 1st 2021, its website at https://www.nycourts.gov/ and related communications, please advise the employer that I am not required to accept these or any accommodations under Title I of the ADA, 29 CFR Part 1630.9(d). Moreover, I am not required to prove any "exemption" but the employer alone has the burden of proving that I am a direct threat. I demand to review the records the employer has relied upon to determine that I am a direct threat. If there is some legal authority that overrides my rights under the ADA, please provide me with a legal citation.

Be advised that 29 CFR Part 1630 prohibits state agencies (employers) from requiring medical examinations or making disability-related inquiries of employees unless such examination or inquiry is shown to be job-related and consistent with business necessity under 42 U.S.C. §12112(d)(4); 29 CFR §1630.14(c)

I have several questions that I would like answered by my employer and I request Eva Moy to incorporate getting them answered as part of the OMIGBM investigation.

**My questions for my employer are:**

1. Why do you regard me as having a disability and what records have you made of this?

2. What physician, what medical records, and what complaint made by a physician to a health officer, and "orders of isolation and quarantine" do you rely upon for diagnosing me as having a contagious disease? Please include all, evidence, court records and records from the individualized assessment used in making this determination or diagnosis as required under Title I of the Americans with Disabilities Act.[2]

3. Please identify the statute and regulation imposing your legal duty of care that requires you to protect me and others from any contagious disease.

4. Please provide a copy of documentary evidence from the departments of health or labor establishing the existence of a disease that has been isolated by modern scientific standards and documentary evidence proving that such disease is airborne, deadly and contagious.

5. Please identify your insurable risk with a copy of your insurance binder showing that you are insured for protecting employees from a contagious disease, and any adverse health consequences they may suffer as a result of your accommodation measures.

6. Regarding the accommodation measures, **a)** why have you refused to include notice that these are made under an emergency use authorization period, and refused to disclose the risks and benefits of the product, and also advise me of my right to either accept or refuse the product,[3] and **b)** which of these accommodation measures has the proven efficacy to prevent transmission or infection of the contagious disease for which you regard me as having?

7. How are your requests for my medical information and submitting to medical examinations and interventions necessary for the performance of my employment duties?

8. Why are you able to diagnose me with a deadly disease and impose restrictions and medical interventions without my informed consent, without any physician's oversight or judicial approval, yet I am required to obtain written permission from my physician to exercise my rights to informed consent and medical privacy? We can stipulate that I have never waived any of my rights to medical privacy which includes the right of informed consent as a condition for employment.

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2 29 CFR 1630.2 *et seq.* And 45 CFR Part 84.2 *et seq.*

3 21 USC 360bbb-3

9. Please disclose records of the court's budget approval for using public funds for administering or prescribing health control measures without judicial oversight and approval, without any licensing, insurance or medical training and without the supervision of any physician.

Be advised that it is illegal to condition my employment upon submitting to accommodation measures, this constitutes discrimination based upon disability, a violation of 29 CFR Part 1630, for which I would have a claim for employment discrimination based upon disability.

Sincerely,

Colleen Mone

attached:
Memo dated September 1, 2021 "Mandatory Testing Program"
Memo dated September 10, 2021 "Mandatory Vaccination Requirement"
Letter dated September 20, 2021 "Employment Discrimination and Retaliation Based on Disability"

**From:** cgrima11@nycourts.gov,
**To:** c.mone@aol.com,
**Cc:** MIGBM@nycourts.gov,
**Subject:** RE: N Discrim -Colleen Mone #2.pdf
**Date:** Wed, Sep 22, 2021 11:31 am

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Ms. Mone,

As indicated in my email to you on September 16, 2021, I have referred this matter to the Office of the Inspector General.

Accordingly, it is not appropriate for me to be copied or otherwise included on any further correspondence/communications regarding same.

Regards,

Carolyn Grimaldi, Esq.

Director of Human Resources

Office of Court Administration

25 Beaver Street, 7th Floor

New York, NY 10004

Tel: (212) 428-2515

**From:** c.mone <c.mone@aol.com>
**Sent:** Tuesday, September 21, 2021 9:14 PM
**To:** Carolyn Grimaldi <cgrima11@nycourts.gov>; MIGBM <MIGBM@nycourts.gov>
**Subject:** N Discrim -Colleen Mone #2.pdf

Ms Grimaldi,

Ms Moy,

Please see attached

Thank you

Colleen Mone

Civil Rights Division

*Disability Rights Section – 4 Con*
*950 Pennsylvania Ave, NW*
*Washington, DC 20530*

December 7, 2021

**VIA EMAIL:c.mone@aol.com**

Colleen Mone
83 Windsor Road
Staten Island, NY 10314

Re: EEOC Charge Against: New York State Unified Court System
EEOC No.: 520-2022-00660

Dear Ms. Mone:

**NOTICE OF RIGHT TO SUE WITHIN 90 DAYS**

Because you filed the above charge with the Equal Employment Opportunity Commission, and the Commission has determined that it will not be able to investigate and conciliate that charge within 180 days of the date the Commission assumed jurisdiction over the charge, and the Department has determined that it will not file any lawsuit(s) based thereon within that time, and because you or your attorney has specifically requested this Notice, you are hereby notified that you have the right to institute a civil action against the above-named respondent under Title I of the Americans with Disabilities Act of 1990, 42 U.S.C. 12111, et seq. If you choose to commence a civil action, such suit must be filed in the appropriate court within 90 days of your receipt of this Notice. This should not be taken to mean that the Department has made a judgment as to whether or not your charge is meritorious.

If you or your attorney has any questions concerning this matter or wish to inspect the investigative file, please address your inquiry to: New York District Office, U.S. Equal Employment Opportunity Commission. Please note, due to COVID-19 there may be a delay in obtaining copies of the case file.

Enclosed you will find a Notice of Rights under the ADA Amendments Act of 2008 (ADAAA). We are forwarding a copy of this Notice of Right to Sue to the Respondent in this case.

Sincerely,
Kristen Clarke
Deputy Assistant Attorney General
Civil Rights Division

BY: /s/ Celeste A. Adams-Simmons
Celeste A. Adams-Simmons
Senior Investigator
Disability Rights Section

Enclosures:
Notice of Rights under the ADAAA

cc: New York State Unified Court System
EEOC- New York District Office

# Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff

## *FINAL GUIDANCE*

*Additional copies are available from:*
*Office of Combination Products*
*Food and Drug Administration*
*WO32, Hub/Mail Room #5129*
*10903 New Hampshire Avenue*
*Silver Spring, MD 20993*
*(Tel) 301-796-8930*
*(Fax) 301-847-8619*
*http://www.fda.gov/CombinationProducts/default.htm.*

For questions regarding this document contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Office of Combination Products**
**Office of Special Medical Programs**
**Office of the Commissioner**

**September 2017**

# Table of Contents

# Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page of this guidance.

## I. INTRODUCTION[1]

FDA regularly receives questions from medical product sponsors concerning the classification of their products.[2] We believe that efficient, effective regulation is facilitated by providing guidance on issues frequently raised in relation to Requests for Designation (RFDs) and other classification activities. In addition, providing as much clarity and predictability as possible with respect to product classifications should enable informed planning for product development. Accordingly, we have prepared this guidance to make the Agency's current thinking concerning certain product classification issues more readily and widely available.

While issues have arisen relating to whether a product should be classified as a drug, device, biological product, or combination product, most of these issues have related to whether a product should be classified as either a drug or a device.[3] Accordingly, this guidance focuses particularly on cases in which a product[4] may be classified as a drug or device.[5] This guidance also addresses additional issues relating to product classification, including how to obtain classification determinations from FDA for medical products.

This guidance is organized into two substantive sections.

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[1] This guidance has been prepared by the Office of Combination Products in consultation with the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research.

[2] Please note that "classification" as used in this guidance refers to a product's designation as a drug, device, biological product, or combination product. This is distinct from the use of the term "classification" in reference to the class (Class I, II, or III) of a device as described in section 513(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

[3] This guidance addresses the definitions for the terms drug, device, and biological product in section III. The term "combination product" is defined in 21 CFR 3.2(e). For further information regarding the definition for the term combination product and the regulation of combination products, please visit the webpage for the Office of Combination Products at www.fda.gov/CombinationProducts/default.htm.

[4] The guidance's discussion of the classification of products is also relevant to classification of the constituent parts of a combination product.

[5] This guidance focuses on classification of products for human use. Distinct considerations may apply in determining how to classify a product intended for use in animals.

Section II offers guidance on the RFD process for obtaining a formal determination of a product's classification.

Section III presents general concepts regarding FDA's decision-making process for classification determinations and addresses issues that may arise in determining whether products should be classified as drugs or devices.[6]

The Agency recommends that sponsors contact the Office of Combination Products (OCP) to confirm the classification of any products they may wish to market if the appropriate classification is unclear or in dispute. Section IV provides contact information for OCP and responses to frequently asked questions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

## II. WHAT IS THE PROCESS FOR OBTAINING A FORMAL CLASSIFICATION DETERMINATION FOR A PRODUCT?

If the classification of a product as a drug, device, biological product, or combination product is unclear or in dispute, a sponsor can submit an RFD to OCP in accordance with Part 3 of Title 21 of the Code of Federal Regulations (21 CFR Part 3) to obtain a formal classification determination for the product, as provided for under section 563 of the FD&C Act (21 USC 360bbb-2). Any RFD determined to be incomplete will be returned to the sponsor with a request for the missing information.[7] 21 CFR 3.8(a). Once OCP determines the RFD is complete for filing, the Agency reviews the RFD.

The sponsor recommends a classification in the RFD, and should explain the basis for the recommendation. While the sponsor should justify why it believes the product meets the recommended classification, we generally consider both the information provided in the RFD and other information available to the Agency at that time in making our designation.

Generally, OCP will respond to the sponsor in writing within sixty days of the RFD filing, identifying the classification of the product as a drug, device, biological product, or

[6] This section generally focuses on approaches for determining whether a product should be classified as a drug or a device, based on application of the statutory definitions for these terms under sections 201(g) and 201(h) of the FD&C Act (21 USC 321(g) and (h)), respectively. Please note that this document does not focus on the classification of products as biological products regulated under section 351(i) of the Public Health Service Act (PHS Act) (42 USC 262(i)). It also does not address under what circumstances certain human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR Part 1271, are regulated solely under section 361 of the PHS Act. For guidance concerning HCT/Ps, please visit http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/.

[7] See 21 CFR 3.7 for content requirements for RFDs.

combination product. If the Agency does not provide a written response within sixty days, the sponsor's recommendation respecting the classification of the product is considered to be the final determination. 21 USC 360bbb-2(b) and (c).

RFD determinations pertain only to the product as described in the designation letter, including its proposed use(s) or indication(s) for use. The Agency may modify a determination made under section 563 regarding the classification of a product or the component of FDA that will regulate the product either with the written consent of the sponsor or for public health reasons based on scientific evidence. 21 USC 360bbb-2(b) and (c).[8]

A new determination may be appropriate if there is a change in, for example, a proposed indication for use or in a component of the product, or if the sponsor or Agency becomes aware of additional information that reveals that the means by which the product achieves its primary intended purposes differ from what was originally described in the RFD. For example, if a sponsor wished to change the indication for a product and that new indication would be achieved through a different mechanism than the original indication, a different classification for the new indication might be appropriate.

Please contact OCP if you have questions regarding whether to submit an RFD, what information to provide, or issues to address in an RFD to ensure its completeness and clarity.[9]

## III. WHAT DOES FDA CONSIDER IN DETERMINING WHETHER TO CLASSIFY A PRODUCT AS A DRUG OR DEVICE?

FDA's determination of whether to classify a product as a drug or device is based on statutory definitions, as set forth in sections 201(g) and 201(h) of the FD&C Act, respectively. We apply these definitions to products, relying on the scientific data that are available to FDA at the time of the classification determination concerning the product for its proposed use(s)/indication(s).[10]

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[8] The sponsor may request reconsideration of the decision if its classification recommendation is not adopted by the Agency. See 21 CFR 3.8, 10.75. If the sponsor develops or becomes aware of new information that may affect the product's classification, the sponsor may also submit a new RFD seeking a new determination.

[9] More detailed information on the RFD process is provided in OCP's guidance *How to Write a Request for Designation (RFD), available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm. A pre-RFD process is available if a sponsor wishes to obtain a preliminary, non-binding classification determination or to engage in preliminary classification discussions with the Agency before filing a formal RFD. The RFD and pre-RFD processes are also available to sponsors to clarify the Center assignment for medical products, though this issue is beyond the scope of this guidance. More information about the pre-RFD process is available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf.

[10] If a product type has been classified by regulation, FDA would generally classify the product (including as a constituent part of a combination product) in accordance with the regulation, if the product (or constituent part) falls within the scope of that regulation. If the Agency concludes that it may be appropriate to propose changing a classification established by regulation, FDA would initiate notice and comment rulemaking to do so.[11] The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

Medical product classification determinations often focus substantially on whether a product that meets the definition of drug also meets the statutory definition of device. This section presents the drug and device definitions and discusses how the Agency addresses certain issues that arise when determining whether a product should be classified as a drug or device.

## A. Statutory Definitions

### 1. Drug

Section 201(g) of the FD&C Act (21 USC 321(g)) provides that the term "drug" means:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). . . .

### 2. Device

Section 201(h) of the FD&C Act (21 USC 321(h)) provides that the term "device" means:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

## B. Certain key provisions of the definition of device

Conceptually, all FDA-regulated medical products meet the definition of "drug" under section 201(g) of the FD&C Act, due to the broader scope of the drug definition. For a medical product also to meet the more restrictive device definition under section 201(h) of the FD&C Act, it must (i) be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," and (ii) "*not* achieve its primary intended purposes through *chemical action* within or on the body of man or other animals" and (iii) "*not* [be] dependent upon being *metabolized* for the achievement of its primary intended purposes" (emphasis added).

The sponsor presumably has the most complete information relevant to how its proposed product achieves its primary intended purpose(s). Sponsors seeking a classification determination should present all available data and other information potentially relevant to that determination (without regard to whether the data or information supports the sponsor's preferred outcome). For example, for a sponsor seeking to classify its proposed product as a device, those data should demonstrate that its product meets the definition of a device.

At the classification stage, sponsors would not be expected to have gathered sufficient data to demonstrate that their proposed product meets the applicable marketing authorization standard (e.g., data demonstrating effectiveness). Therefore, the focus of FDA's classification analysis is on how the product would be expected to achieve its primary intended purposes, assuming it is capable of achieving its primary intended purposes at all. FDA will use its best scientific judgment to evaluate all available information relevant to the classification determination, including information submitted by the sponsor or available in the literature.

The following discussion presents the Agency's current thinking on certain issues that arise with respect to the statutory definition of device.

### 1. "Similar or related article" in the definition of device

The first clause of the device definition provides that the term "means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or *other similar or related article* . . ." (emphasis added). The issue of whether a product may be considered a "similar or related article" under this clause can arise, for example, with regard to products in liquid, semi-liquid, gel, gas, or powder form. In some cases, such products are appropriately considered "similar or related articles," and may be classified as devices, so long as they also satisfy the remainder of the device definition under section 201(h) of the FD&C Act, including the chemical action exclusion discussed in section III.B.3 below. This could be the case, for example, for gels or powders put on the skin as a barrier, gases used as space fillers, or liquids used to clean either surgical instruments or contact lenses.

### 2. "Primary intended purposes" in the definition of device

Most often, in determining whether a product meets the device definition, questions arise concerning the exclusionary clause of the definition, which provides that a device is a product "which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals . . . ."[11] A product that has chemical action could be a device if it does not achieve its primary intended purposes through that chemical action.

[11] The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

For example, if the primary intended purpose of a hip joint replacement implant is to restore movement, and the implant also elicits a foreign body response through chemical action, that response would not be considered a primary intended purpose of the implant. Accordingly, such an implant could be classified as a device despite the chemical action, because such action does not achieve the product's primary intended purpose. Similarly, if the primary intended purpose of an absorbable suture is to rejoin tissue, and the suture is also designed to be resorbed by the body through a combination of chemical action and metabolic activities, such resorption would not be considered a primary intended purpose of the product. Accordingly, such an absorbable suture could be classified as a device despite the chemical action and metabolic activity, because such action or activity does not achieve the product's primary intended purpose.

### 3. "Chemical action" in the definition of device

FDA frequently receives questions from product sponsors concerning the Agency's interpretation of the term "chemical action." This term must be read in the context of the statutory definition of "device" as a whole. The determination of whether a product meets the device definition does not depend solely on whether the product exhibits "chemical action." In particular, as explained in section III.B.2 and 4, a product that exhibits chemical action will still meet the device definition if the product "does not achieve its primary intended purposes through" that chemical action "within or on the body," and otherwise satisfies the device definition.

Under the Agency's interpretation of the device definition, a product exhibits "chemical action" if it interacts at the molecular level with bodily components (e.g., cells or tissues) to mediate (including promoting or inhibiting) a bodily response, or with foreign entities (e.g., organisms or chemicals) so as to alter that entity's interaction with the body.[12] We note that this type of interaction is consistent with the term "pharmacological action" as that term is generally understood in the medical field. Accordingly, we have used "pharmacological action" as a shorthand throughout the rest of this guidance for ease of explication and recognition. The examples presented in section III.B.5 offer illustration of FDA's interpretation of chemical action.

### 4. "Within or on the body" in the definition of device

Because a device "does not achieve its primary intended purposes through chemical action *within or on the body* of man or other animals" (emphasis added), a product can be a device even if it achieves its primary intended purposes through chemical action, so long as the chemical action does not occur "within or on the body" (and the product meets the other elements of the definition of device under section 201(h)).

Whether chemical action is occurring "within or on the body" is generally a straightforward matter. If the chemical action is occurring inside the body or on the surface of the body, it is within or on the body. For example, the chemical action of an orally ingested pill

[12] For purposes of this interpretation, an interaction at the molecular level occurs through either chemical reaction (i.e., formation or breaking of covalent or ionic bonds), intermolecular forces (e.g., electrostatic interactions), or both. The mere exchange of non-chemical energy (e.g., electromagnetic or thermal energy) between a product and the body would not constitute "chemical action."

or tablet of a decongestant would be "within the body," and the chemical action of a spray or cream for treatment of dermatitis when applied to the skin would be "on the body." Similarly, it is generally a straightforward matter to determine that chemical action is not occurring within or on the body. For example, the chemical action of an antimicrobial agent used to clean a surgical instrument before that instrument is used is not occurring within or on the body.

However, the Agency has on occasion considered some situations in which it may be less clear whether chemical action is occurring within or on the body. For example, we have determined that chemical action occurring solely within an extracorporeal device, specifically a kidney hemodialysis machine, is not occurring within or on the body. Similarly, we have determined that the chemical action of a transport solution to preserve a donor organ for transplantation while in an organ transport container is not occurring within or on the body.

### 5. Illustrative Examples

The following examples further illustrate the application of some of the key provisions of the device definition discussed above. Table 1 contains some examples of medical products that achieve their primary intended purposes through chemical action within or on the body. Table 2 contains some examples of medical products that do not achieve their primary intended purposes through chemical action within or on the body.

**Table 1: Examples of Medical Products that Achieve Their Primary Intended Purposes through Chemical Action within or on the Body**

| Product | Description |
|---|---|
| Aspirin | Aspirin is used for pain relief. Acetylsalicyclic acid (aspirin) contains an acetyl group that has the ability to covalently bind to a serine residue of a cyclooxygenase enzyme (COX-1 or COX-2). This is considered pharmacological action because it inactivates the enzyme and thereby inhibits the synthesis of prostaglandin and thromboxanes, which suppresses the body's inflammatory response for pain relief. |
| Beta Blockers | Beta blockers are used to reduce blood pressure. Cells contain beta receptors that can be stimulated by neurotransmitters such as adrenaline/epinephrine. Beta blockers, like propranolol, bind beta receptors (b1 and b2) and exhibit pharmacological action by inhibiting the activation of the signaling cascade. This blockage causes cardiac cells to reduce the strength of cardiac contractions and heart rate. |
| Magnesium Sulfate | Magnesium sulfate is used as replacement therapy for magnesium deficiency. It acts as a catalyst in enzymatic reactions (a molecular-level interaction). While the chemical or atomic structure of magnesium sulfate is not altered, its participation in enzymatic reactions is considered a pharmacological action because it impacts various cellular and molecular processes. |

| | |
|---|---|
| Polymyxin B Sulfate | Polymyxin B sulfate is an antibiotic that is used to treat bacterial infection. It is composed of a cationic protein surfactant that has fatty acid functional groups. Polymyxin B sulfate acts through intermolecular forces, by binding to components of the bacterial membrane (i.e., the membrane of the foreign entity) and by association/fusion of the fatty acid portion of the molecule with the lipid bilayer via hydrophobic interactions. This binding is a pharmacological action because it disrupts the integrity of the bacterial membrane, which causes organism death, thereby treating the bacterial infection. |
| Hydroxocobalamin | Hydroxocobalamin is used as an antidote to cyanide poisoning. The cobalt moiety of hydroxocobalamin exhibits pharmacological action because it chemically reacts with cyanide, a toxic chemical agent, to form cyanocobalamin, a non-toxic compound, and the ability of hydroxocobalamin to interact with cyanide facilitates the removal of the toxic agent in order to inhibit the toxic effects of cyanide on the body. |

**Table 2: Examples of Medical Products That Do Not Achieve Their Primary Intended Purposes through Chemical Action within or on the Body**

| Product | Description |
|---|---|
| Abdominal Adhesion Barrier | Inert, biodegradable synthetic polymers can be used to reduce post-operative adhesions with tissues and organs within the abdominal cavity. An implanted physical barrier sheet composed of such polymers would act to reduce adhesion through physical separation of tissue and not through pharmacological action on the surrounding tissue. |
| Polymethylmethacrylate (PMMA) | PMMA is an acrylate polymer that is used as a temporary bone spacer. PMMA is built from methyl methacrylate monomer units, which undergo free radical polymerization in the presence of an initiator compound. The molecules that are part of the polymerization process interact with each other to create a solid mass to fill a bone void physically. The process does not require an interaction between the PMMA and the bone at the molecular level and, therefore is not considered chemical action within or on the body. |
| Topical Surgical Adhesive | Cyanoacrylate is an acrylic resin that is used to approximate skin tissue as an adjunct to a wound closure product. The resin undergoes anionic polymerization in the presence of water. The chemical reaction that occurs between the resin and ions in the water allows it to form into long polymer chains. This type of adhesive can bond to a cut/incision, creating a physically-intact film to aid in keeping skin edges together. While the product binds to tissue, it does not exhibit pharmacological action because that binding does not mediate a bodily response. |

| | |
|---|---|
| Gold Nanoparticles | Nanoparticles composed of gold can be used to treat cancer. When gold nanoparticles are injected into a tumor site and exposed to electromagnetic energy, they absorb the electromagnetic energy and convert it to thermal energy, and this heat is transferred to the surrounding cells or tissue. The heat transfer, as opposed to a binding interaction with the nanoparticle, causes the cancer cells to die. Therefore, this effect is not achieved through chemical action. |
| Cryosurgery for Wart Removal | Cryogen (liquid gas), such as nitrogen or dimethyl ether, is used to treat common and plantar warts. The liquid gas is extremely cold and freezes the wart, resulting in damage to the topmost layer of cells. A physiological effect (i.e., cell death) results from heat transfer, not from a binding interaction with the gas. Therefore, the freezing is not considered chemical action. |
| Dental Amalgam | A resin that fills a cavity in a tooth as part of the treatment of dental caries may bind to the tooth via covalent bonding, or rely in part on intermolecular forces to change from liquid or paste to solid form. However, this binding and/or state change does not mediate a bodily response, but rather produces a solid mass, to fill the cavity. Therefore, it would not be considered chemical action. |
| Respirator Mask with Antimicrobial Filter | An antimicrobial product impregnated into a filter on a respirator mask to kill microbes that the user might otherwise inhale would exhibit pharmacological action. However, while the mask is in contact with the user's face, the filter is not. So, the chemical action occurring on the filter is not occurring within or on the body. |

### C. How is a product classified if it meets the definition for drug (or for both drug and device) and also meets the definition for biological product?

As explained in section III.B, products that meet the device definition in 201(h) of the FD&C Act also meet the drug definition in 201(g) of the FD&C Act. In addition, products that meet the drug definition, or both the drug and device definitions, may also meet the definition of biological product under section 351(i) of the PHS Act (42 USC 262(i)).

Section 351(i) provides that:

> The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide),[13] or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[13] For guidance on FDA's interpretation of the category "protein (except any chemically synthesized polypeptide)" see *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, at Q.II.1 (April 2015), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf.

Products that meet the drug definition and that also meet the definition of biological product are classified as biological products, and are generally subject to licensure under the PHS Act.[14] Products that meet the definitions for drug, device, and biological product may also be classified as biological products. If you have questions regarding whether a product meets the definition of biological product or how this might affect its classification, please contact OCP.

## IV. ADDITIONAL INFORMATION

For further information on the classification of products as devices, drugs, biological products, or combination products, please refer to the Frequently Asked Questions on the next page, OCP's webpage at https://www.fda.gov/CombinationProducts/default.htm or contact OCP at:

Office of Combination Product
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993

(Tel) 301-796-8930
(Fax) 301301-847-8619
combination@fda.gov

[14] Certain biological products have been historically approved under the FD&C Act and may continue to be subject to approval under the FD&C Act until March 23, 2020. See Section 7002(e) of the Biological Price Competition and Innovation Act of 2009; see also FDA, *Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009, available at* https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm490264.pdf.

## FREQUENTLY ASKED QUESTIONS

1. Can a product be classified as a device if it exhibits "chemical action"?

   Yes, if the product does not achieve its primary intended purposes through chemical action within or on the body and otherwise meets the definition of a device. However, products that meet the device definition may be regulated as drugs or biological products in some cases. See question 2.

2. If a product meets the definition for drug at 21 USC 321(g) and for device at 21 USC 321(h), how is it classified?

   Generally, the product would be classified as a device, unless it falls within a special category (for example, apparatuses used in the preparation of compounded positron emission tomography drugs are classified as drugs, see 21 USC 321(ii)).

3. Can the proposed use or indication of a product affect its classification?

   Yes. Two products with exactly the same composition can be classified differently based on their primary intended purposes. For example, if a vaginal product is intended solely to facilitate ease and comfort during sexual intercourse and it achieves this through lubrication that decreases friction (via mechanical/physical action) and not through chemical action, it is classified as a device. However, the same product can be classified as a drug if it is intended, for instance, to alter pH, control odor, or prevent infection, and does so through chemical action as discussed in III.B.3 above.

4. What should you do if, after reviewing this guidance, you are unsure of how your product is classified?

   You should contact the Office of Combination Products (Combination@FDA.GOV) for feedback. OCP will provide you feedback, including on whether a pre-RFD or an RFD may be appropriate and what information you should provide.

5. Where can you find additional information about product classification?

   Additional information on classification is posted on OCP's webpage at:(https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm)

   For additional information on how to submit an RFD, see *How to Write a Request for Designation (RFD)* (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm).

   More information about the pre-RFD process is available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf .

**TITLE:** NEW YORK STATE COURT OFFICER

**Effective Date:** 01/08/2004
**Title Code Number:** 9467001
**Salary Grade:** 18
**Jurisdictional Classification:** C

**DISTINGUISHING FEATURES OF WORK:**

Under the direct supervision of a New York State Court Officer-Sergeant and the general supervision of the court clerk or other security supervisory personnel, New York State Court Officers are responsible for maintaining order and providing security in courtrooms, court buildings, and grounds. NYS Court Officers are assigned to all trial courts and court agencies. NYS Court Officers are peace officers, required to wear uniforms, and may be authorized to carry firearms, execute warrants, make arrests and may coordinate the activities of other court security personnel.

**TYPICAL DUTIES:**

Provides security by standing in the courtroom and patrolling the courthouse.

Guards criminal defendants accused of both misdemeanors and felonies while in the courtroom and may escort them to and from detention pens.

Assumes a post or patrols the courthouse to maintain order by removing or calming disruptive individuals; bars entry into security areas or courtrooms of people not properly attired or behaved; talks to potentially disruptive prisoners or spectators to calm them.

Physically restrains unruly individuals.

Arrests individuals according to established procedures.

Escorts, guards, and delivers material to sequestered juries.

Escorts judges, juries, witnesses and prisoners to and from the courtroom.

Administers first aid and assistance to individuals during emergencies, accidents or illnesses.

Provides assistance in emergency situations.

Operates security equipment, including magnetometers, handheld screening devices and package x-ray machines.

Uses established search procedures to assure that no weapons or electronic or photographic equipment are brought into the courtroom.

Checks to ensure that all necessary documents are available prior to court sessions.

Checks bench to ensure that Judge has adequate supplies, proper forms, and other materials.

Displays and safeguards exhibits in the courtroom.

Maintains and updates court records.

Distributes and posts appropriate documents and court materials.

Checks any emergency or special equipment such as oxygen tanks, walkie-talkies, and other items to ensure that the equipment is in good working order; reports inoperative equipment to supervisor.

Provides general information to visitors on court premises.

Prepares incident reports.

*The above statements are intended to describe the general nature and level of work being performed by persons assigned to this title. They do not include all job duties performed by employees in this title, and every position does not necessarily require these duties.*

**KNOWLEDGE, SKILLS, AND ABILITIES:**

Knowledge of court procedures and practices, court forms, and legal terminology.

Knowledge of laws concerning arrest, use of physical force, and search procedures.

Knowledge of regulations and procedures for handling prisoners.

Knowledge of first-aid.

Knowledge of the rules of evidence and the proper procedures for handling evidence and exhibits.

Knowledge of the laws, rules and regulations concerning weapons and the use of firearms.

Knowledge of regulations and procedures for handling prisoners.

Skill in completing and organizing court documents, forms, and other records.

Skill in administering first aid and using emergency equipment.

Skill in conducting searches and using security equipment.

Skill in using weapons.

Ability to apply knowledge, prior experience, facts, rules, regulations, and directions to specific situations.

Ability to identify and evaluate situations, events and conditions relating to observable activities.

Ability to exercise judgement and common sense.

Ability to carry out established security procedures in case of fire, bomb threat, or other emergency situations.

Ability to observe detail, remember facts and information, and evaluate situations.

Ability to understand oral and written instructions and apply information, rules, regulations, and procedures, to specific situations.

Ability to prepare brief written communications.

Ability to communicate information orally to the public and court or court-related personnel.

Ability to stand and walk for lengthy periods.

Ability to use firearms, self-defense and restraint techniques, and security equipment.

Ability to supervise other workers and to check staff performance.

**RELATED TITLES:**

| *Title* | *Position in Title Series* | *Distinguishing Characteristics* |
|---|---|---|
| New York State Court Officer-Trainee (JG-14) | Entry Level | Serves a two year traineeship. |
| **New York State Court Officer (JG-18)** | **Mid-level (Automatic promotion)** | **Provides court security in courtrooms, court buildings and grounds.** |
| New York State Court Officer-Sergeant (JG-19) | Entry level Supervisor (Promotional) | Supervises security team of subordinate security personnel, provides on the job training and evaluates the performance of subordinates. |
| New York State Court Officer-Lieutenant (JG-22) | Supervisory (Promotional) | On-site supervisor second in charge to New York State Court Officer-Captain. |

**QUALIFICATIONS:**

At the time of appointment, a New York State Court Officer candidate must have served a two year traineeship as a New York State Court Security Trainee.

Candidates must be legally eligible and qualified to carry firearms.

New York State residency is required for appointment.

Candidates must be citizens of the United States.

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